University Of Alberta

EVALUATING A NEW FOOT DROP STIMULATOR FOR STROKE PATIENTS

BY

SAAD C. NAAMAN

A thesis submitted to the Faculty Of Graduate Studies and Research in partial fulfillment of the requirements for the degree of

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August 29, 1996

To my Parents,

for they showed me the way by their love

To my Teachers,

for they enlightened the way for me by their guidance and knowledge

ABSTRACT

EVALUATING A NEW FOOT DROP STIMULATOR FOR STROKE PATIENTS

Stroke is the leading cause of disability in the elderly. The objective of this study is to test a system of externally applied Functional Electrical Stimulation (FES) system for adult stroke patients and evaluate its effect on gait, walking efficiency, and patients' satisfaction with FES. Patients used the system for 6 weeks during which they were assessed every 2 weeks. Seven patients with hemiplegia were recruited from Glenrose Rehabilitation Hospital. Gait analysis was done at each visit with and without stimulation and with an ankle foot orthosis (AFO) for subjects who had previously used an AFO. There was a statistically significant difference in the swing/stance ratio towards correction of gait ($p<0,05$) with FES. No statistically significant changes in walking efficiency with and without FES and in speed, stride length, and cycle duration. All patients want to continue using the device and no user has dropped out of the study. Discomfort is one of the limitations of FES. It can be minimized by adjusting the appropriate stimulus parameters. Proper selection and support to patients using FES are essential in its successful clinical application.

PREFACE

Stroke is the leading cause of disability among adults in North America and many other developed countries and the importance of this disorder is increasing as the population ages. Stroke rehabilitation is a restorative and learning process which seeks to hasten and maximize recovery from stroke by treating the resultant impairments, disabilities, and handicaps. It attempts to help the patient regain freedom of movement and functional independence and to integrate as fully as possible into community life.

Functional Electrical Stimulation (FES) is one of the technologies used for upper and lower extremity movement, and several other applications in rehabilitation medicine. Since its first clinical application more than 30 years ago by Liberson et al in 1960, many modifications have been developed and evaluated, but its clinical application remains limited.

I had the chance to work with a team developing medical devices for rehabilitation purposes in stroke and spinal cord injured patients. My main project was to study one of the clinical applications of FES, the use of a single channel foot drop stimulator for stroke patients. The objectives of the study were to test the use of this simple FES system, the effect it has on gait, walking efficiency, and the subjects' general acceptance, compliance, use, and benefits from this system.

To have a better understanding of the role of FES in stroke rehabilitation, an overview of stroke, its risk factors, pathology, etiology, management principles, and orthotics used in stroke is given in the first chapter. Functional Electrical Stimulation as one of the rehabilitation treatment modalities and the literature relevant to its application in the lower extremity is discussed. In the second chapter a clinical trial is described testing the WALKAID, a one channel foot drop stimulator developed at the Division of Neuroscience. The effect it has on gait improvement and comparisons with an ankle foot orthosis are presented.

Discomfort being one of the limitations of FES application, we did a study on minimizing the discomfort caused by FES by changing the different stimulus parameters which is discussed in the third chapter. The clinical trial is part of an on-going study with the objective of studying a larger number of subjects using the foot drop stimulator as an FES application in stroke patients.

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ABBREVIATIONS

ADL= Activity of Daily Living
AFO= Ankle Foot Orthosis
AHCPR= Agency for Health Care Policy and Research
CNS= Central Nervous System
CVA= CerebroVascular Accident
EMG= Electromyography
FES= Functional Electrical Stimulation
NS= Normal Subject
NIS= Neurologically Impaired Subject
ROM= Range Of Motion
TIA= Transient Ischemic Attack

CHAPTER 1 - GENERAL INTRODUCTION

1.1 STROKE

1.1.1. Definition

Stroke is defined as an acute neurological dysfunction of vascular origin with symptoms and signs corresponding to the involvement of focal areas of the brain; alternatively, the rapid onset of a neurological deficit that persists for at least 24 hours and is caused by intracerebral or subarachnoid hemorrhage or the blockage of a blood vessel supplying or draining the brain. Transient ischemic attack (TIA) is defined as an episode of focal cerebral dysfunction lasting less than 24 hours, generally due to a vascular mechanism (Agency for Health Care Policy and Research [AHCPR] 1995, Folger 1987).

1.1.2 Epidemiology of Stroke

Stroke is the leading cause of disability in the elderly and a significant cause of disability in younger people. It is the third leading cause of death in the United States after coronary heart disease and cancer.

The average age-adjusted incidence rate of first strokes has been reported to be 114 per 100,000 but ranges from 81 to 150 per 100,000 in different studies (Terént 1993). There are over 3 million patients who have sustained a stroke alive in the United States today. According to the Rochester, Minnesota study, stroke prevalence is 500 to 800 cases per 100,000 population. These figures are similar to those of other countries (Terént 1993). The AHCPR clinical guidelines report summarizes the different studies on epidemiology in the Post Stroke Rehabilitation manual as the incidence of stroke being 500,000, prevalence 2,980,000 and mortality 147,470.

In most studies the average female/male incidence ratio is close to one (Terént 1993). While other studies have shown that men have 30 to 80 percent higher rates than women (Broderick et al 1989, Wolf, et al 1992, Millikanet al 1987).

The incidence of stroke doubles with every decade after 55 years of age. In the Rochester, Minnesota study there was a nine fold increase in the incidence of stroke between ages 55 to 64 (Broderick et al 1989).

First-ever strokes account for about 75% of the acute events and recurrent strokes for about 25% (Terént 1993).

According to the National Hospital Discharge Survey between the years 1980-1989, there were approximately one million discharges a year which have stroke listed as the primary diagnosis (Cardiovascular Disease Surveillance, Stroke, 1994).

Stroke is the most common neurological disability and represents a burden on the health cost (Smurawaska et al 1993, Barnett et al 1995). It costs the Canadian economy 1.5 billion dollars per year in terms of health expenditure and lost productivity (Veloso 1993). The estimated cost of acute and long term care for such patients in the United States is approximately $30 billion per year (AHCPR 1995, Bronner et al 1995).

Survival of stroke patients substantially improved during the 1980s and 1990s. In a recent study it was found that dying within 2 years after stroke was approximately 40% lower in 1990 than in 1980 (Shahar et al 1995). This increases the number of the people living with a disability and increases the impact stroke has on the health system. It is not possible to determine how much of the decline in mortality is a drop in the incidence rate or how much is the result of improved treatment. Improved treatment of hypertension accounts for much of the decline in stroke incidence, but mortality had been decreasing several years before effective anti-hypertensive treatment became available, so other variables must be involved in this trend (Garrison & Rolak 1993).

1.1.3. Risk Factors:

Age is the main risk factor for stroke. In most age groups, stroke is as common in women as in men. It is the only major complication of atherosclerosis in which men are not at greater risk than women (Garrison & Rolak 1993).

Hypertension is currently the most consistently powerful predictor of stroke. It is a factor in nearly 70% of strokes. Hypertension promotes stroke by aggravating atherosclerosis in the aortic arch and cervicocerebral arteries; causing arteriosclerosis and lipohylanosis in the small-diameter, penetrating end arteries of the cerebrum; and contributing to heart disease, of which stroke is a complication. For people of all ages and both sexes, higher levels of both systolic and diastolic blood pressure have been associated with an increased incidence of ischemic and hemorrhagic stroke (Bronner et al 1995, Garrison & Rolak 1993, Wolf et al 1992, AHCPR 1995).

Cardiac impairment ranks third as a major risk factor in stroke. This is especially true of ischemic coronary heart disease, but nonatherosclerotic heart disease is also an important cause of CVA. The risk of stroke more than doubles in both men and women with coronary heart disease, and congestive heart failure further increases the risk. The heart can serve as a source of emboli that subsequently travel to the brain, so thrombogenic heart diseases other than myocardial infarction also pose a risk. Most important is atrial fibrillation, which even in the absence of rheumatic heart disease or other valvular problems frequently leads to embolization (Folger 1987, Garrison & Rolak 1993, AHCPR 1995).

A *stroke itself* is a risk factor for another stroke. Up to 50% of all CVAs occur in patients who have had previous strokes or TIAs (Garrison & Rolak 1993). *Cigarette smoking* is a major cause of both ischemic and hemorrhagic stroke. Smoking may contribute to stroke by increasing blood levels of fibrinogen and other clotting factors, increasing platelet aggregability, decreasing high-density lipoprotein cholesterol levels, increasing the hematocrit, directly damaging endothelium, which may lead to atherosclerosis and acutely increasing blood pressure, which may promote arterial rupture (Bronner et al 1995).

Epidemiological and clinical evidence support the association of *diabetes* with a higher than normal prevalence of risk factors for cardiovascular disease, such as hypertension, obesity, and dyslipoproteinemia (Bronner et al 1995). In the United States, in the period 1976 to 1980, a medical history of stroke was 2.5 to 4 times more common in diabetics than in persons with normal glucose tolerance test (Wolf et al 1992).

Obesity is often associated with hypertension, elevated lipid levels, carbohydrate intolerance, and cardiac disease. For this reason an increased risk of stroke might be expected (Folger 1987). At present, about one in three adults in the United States is classified as overweight, and the prevalence of obesity has been steadily increasing. Because obesity may increase the risk of stroke by its adverse effects on other risk factors for cardiovascular disease, efforts to reduce weight should be beneficial.
Blood Lipids: for stroke generally and for atherthrombotic brain infarction in particular, the relationship of total serum cholesterol and incidence of disease is neither clear nor consistent (Wolf et al 1992, Folger 1987, Bronner et al 1995). An increase in serum cholesterol could lead to atherosclerosis of the internal carotid artery and the larger cerebral arteries and to subsequent ischemic stroke. A second mechanism, more speculative, involves the weakening of the endothelium of smaller intracerebral arteries due to high serum cholesterol levels. This condition may be further aggravated by hypertension and lead to hemorrhagic stroke (Bronner et al 1995).

Although *family history* of stroke is perceived to be an important marker of increased stroke risk, confirmation of epidemiological studies has been lacking (Wolf et al 1992).

In a few studies, a relationship between *high hematocrit* and the risk of cerebral infarction has been demonstrated. Serum fibrinogen levels has been implicated in the pathogenesis of atherogenesis and arterial thrombus formation and consequently its impact on the incidence of coronary heart disease and stroke (Wolf et al 1992).

The relationship of *alcohol consumption* to stroke occurrence is less clearly elucidated. Available evidence rather uniformly demonstrates an adverse effect of heavy alcohol consumption on stroke incidence. The mechanisms by which moderate alcohol intake may, in fact, be beneficial include a reduction in the risk of coronary heart disease, favorable modification of blood lipid and lipoprotein levels, and inhibition of clotting mediated by increases in prostacyclin levels and activation of the fibrinolytic system (Bronner et al 1995, Wolf et al 1992).

Physical activity: leisure-time and work-associated vigorous physical activity has been linked to lower coronary heart disease incidence (Wolf et al 1992). Although the relation between physical activity and the risk of stroke has not been extensively examined, the results from available studies are quite consistent. Several studies have found a statistically significant inverse relation between physical activity and the risk of stroke in men and women. Physical factors favorably affect risk factors for cardiovascular disease. Exercise tends to decrease the aggregability of platelets, increase sensitivity to insulin, reduce weight, increase high-density lipoprotein cholesterol levels, and lower blood pressure (Bronner et al 1995).

Oral contraceptives: higher dose formulations of oral contraceptives were found to increase the risk of stroke in some subgroups of women, including women over 35 years of age, cigarette smokers, women with hypertension, and women with a history of migraine headaches. In young women with unexplained ischemic stroke, use of contraceptives is presumed to be the "cause" of the infarct; however the stroke was attributed to contraceptives in no more than 10% of a series of carefully studied patients (Wolf et al 1992). There is a suggestion, however, that fewer adverse outcomes were observed in women who took low-dose oral contraceptives than in those who took a high-dose form (Bronner et al 1995).
The identification and awareness of these risk factors has led to the rapid decline in death rates from stroke in the United States and in most other industrialized nations since 1968. In the United States this decline of more than 50% in mortality rates in a 20 year span supports the notion that modifiable environmental influences are operating in stroke and cardiovascular disease occurrence. While coronary heart disease incidence and recurrence can be reduced by cholesterol lowering, there is little evidence that such an effort would directly reduce stroke. Since coronary heart disease is a major precursor of stroke and is the principal cause of death of stroke and TIA survivors, coronary heart disease prevention is certainly worthwhile (Wolf et al 1992).

1.1.4 Clinical Syndromes:

"Stroke" and "Cerebrovascular Accident (CVA)" are used as synonymous in this study. Hemiparesis is the common manifestation of stroke. When describing

hemiparesis, care must be taken to distinguish the anatomy of the brain lesion from the clinical signs and symptoms it causes. The description "left sided stroke" does not convey whether the patient has weakness of the left side of the body or left hemisphere lesion. The use of precise description such as "left hemisphere stroke with right hemiparesis" avoids confusion (Garrison & Rolak 1993).

1.1.5. Types of Cerebrovascular Disease (Adams et al 1993):

1. Atherosclerotic thrombosis
2. Transient ischemic attack
3. Embolism
4. Hypertensive hemorrhage
5. Ruptured and unruptured saccular aneurysm or arteriovascular malformation
6. Arteritis as in infective disorders of the central nervous system or due to connective tissue disease.
7. Cerebral thrombophlebitis
8. Hematologic disorders: poiycythemia, sickle cell disease
9. Trauma to carotid artery
10. Dissecting aortic aneurysm
11. Systemic hypotension with arterial stenoses, simple faint, blood loss etc..
12. Complications of arteriography
13. Neurologic migraine with persistent deficit
14. Associated with tentorial, foramen magnum, and subfalcial herniation
15. Miscellaneous types: fibromuscular dysplasia, radioactive or x-irradiation etc..
16. Undetermined cause as in children and young adults

1.1.6 Anatomy And Etiology

One of the most important clinical determinations in the evaluation of the patient with cerebrovascular disease is whether the symptoms arise from the anterior circulation (i.e. the carotid artery and its main branches, the anterior and middle cerebral
arteries) or the posterior circulation (i.e. vertebral, basilar and posterior cerebral arteries). The pathogenesis, diagnostic workup, therapy, and prognosis of stroke in these two vascular regions are usually different (Garrison & Rolak 1993).

Anterior circulation

The internal and external carotid vessels are located in the neck at the bifurcation of the common carotid artery. Each internal carotid ascends in the neck, enters the skull through the carotid canal, courses through the cavernous sinus where it gives off the ophthalmic artery, then pierces the dura and ends by bifurcating into the middle and the slightly smaller anterior cerebral arteries.

Microembolic TIAs are the most common thromboembolic events associated with atherosclerotic heart disease. Platelet aggregates or atheromatous debris originating from an ulcerated plaque at the carotid bifurcation in the neck are carried centrally into the ophthalmic or middle cerebral artery territories. Transient occlusion of the retinal branches of the ophthalmic artery produces the amaurosis fugax syndrome. There is a uniocular visual loss which persists for seconds or minutes and then clears (Baxter). Cerebral TIAs take the form of equally brief motor, sensory, or visual deficits.

Few signs and symptoms allow a reliable distinction between anterior and posterior ischemia. The circle of Willis permits shunting of blood that can obscure the anatomy of lesion. Eighty percent of strokes occur in the carotid distribution, affecting the cerebral hemispheres and causing a hemiparesis. Hemiparesis or hemianesthesia does not reliably differentiate between anterior versus posterior circulation since the corticospinal tract can be affected anywhere in its path from the cerebral hemispheres including the brainstem.

A. **Middle cerebral artery syndromes**: This vessel supplies the lateral aspect of the frontal, parietal, and temporal lobes and the underlying corona radiata extending as deep as the putamen and the posterior limb of the internal capsule. Most cerebral infarcts of thromboembolic origin develop in the distribution of the middle cerebral artery. The clinical picture of middle cerebral artery occlusion depends on which hemisphere is involved. There is usually less involvement of the leg, and as the patient recovers the patient is able to walk with a spastic, hemiparetic gait. If the left hemisphere is involved the patient initially may initially have global aphasia.

B. **Anterior cerebral artery syndromes**: Cortical branches of the anterior cerebral artery supply the orbit, polar, the median and paramedian regions of the frontal cortex. They supply only a strip of the lateral surface of the hemisphere along the upper border.

Clinical syndromes due to thromboembolic occlusion of an anterior cerebral artery are much less common than middle cerebral artery syndromes. Syndromes caused by microembolization or the development of lacunes in the anterior cerebral distribution are infrequently seen. Intracerebral hemorrhage into one or both frontal polar regions is most commonly due to rupture of an anterior cerebral or anterior communicating artery aneurysm (Baxter 1987).

Posterior Circulation:
The vertebral arteries join at the junction of the medulla and pons to form the basilar artery. The vertebral and the basilar arteries supply the brain stem by paramedian and short circumferential branches. The basilar artery terminates by

bifurcating at the upper midbrain level to form the two posterior cerebral arteries. TIAs of microembolic origin are common in the vertebrobasilar distribution. Microemboli may originate from the aortic arch or from ulcerated atherosclerotic lesions in the vertebral or basilar arteries. Lacunar infarcts are common in the vertebrobasilar distribution. In contrast to cerebral lacunes, few brain stem lacunes are
asymptomatic. This is because of the compact nature of the structures in the brain stem. As a consequence, functional deficits associated with brain stem lesions are common and lacunes can often be sharply localized on clinical grounds (Baxter 1987). Clinical syndromes in the posterior circulation are usually more complex than are those in the hemispheres because the neurological structures in the brain stem are arranged more compactly than those in the cerebral hemispheres. In the brain stem stroke, bilateral signs are frequently present; cranial nerve and cerebellar abnormalities are usually prominent.

The most reliable indication of brain stem disease is cranial nerve dysfunction such as dysarthria, dysphagia, diplopia, or dizziness in conjunction with hemiparesis and hemisensory loss. Deviation of the eyes may also help in distinguishing anterior from posterior circulation stroke. In anterior circulation stroke, damage to the frontal lobe gaze centers causes the patient to look away from the hemiparetic side whereas damage to the pontine gaze center causes deviation towards the hemiparetic side. Stroke to the brain stem with damage to the facial nerve causes paralysis of the entire side of the face, while weakness of the lower half of the affected face suggests damage in the cerebral hemisphere. Dysartharia and dysphagia frequently arise from brain stem lesions but may occur with facial and tongue weakness due to hemispheric damage, so they are unreliable signs.

Differentiating carotid from vertebrobasilar ischemia has practical importance for the patient and physician. The middle cerebral and internal carotid arteries are the major points of attack for atherosclerosis in the cerebrovascular system. Most emboli from the carotid artery or the heart travel to the middle cerebral artery. In contrast, atherosclerosis is less prominent in the posterior circulation and large emboli seldom travel through the vertebral arteries. Evaluation of a patient with carotid ischemia will therefore usually focus on atherosclerotic disease of the neck, sometimes with a consideration of carotid endarterectomy, and on cardiac sources of emboli. In contrast extensive workup of brain stem ischemia is seldom indicated; surgical repair is usually not feasible, cardiac emboli to this region are rare, and therapeutic options are more limited (Garrison & Rolak 1993, Baxter 1987).

The prognosis for posterior circulation strokes may be better than that for strokes in the anterior circulation. Brain stem strokes are often small and patients have

excellent prognosis for recovery. Most patients who survive brain stem strokes recover well, with little functional impairment. The prognosis for recovery from carotid strokes is highly variable and depends on many factors, but in general it is less complete than in brain stem strokes.

Lacunar Syndromes:
The term lacunar syndrome is controversial in that it is used to describe a class of symptoms, or pathology, or both. Four different types of classical lacunar syndromes are seen clinically:
a. Pure motor hemiparesis. This resembles the deep middle cerebral artery syndrome to some degree, with a mild-to-moderate hemiparesis, often stuttering or progressive in onset, involving the face, arm, and leg.
b. Pure sensory stroke. This is defined by sensory symptoms involving an entire side of the body. Most often the complaint is that of paraesthesia and/or dysthesia.
c. Ataxic hemiparesis. This is less easy to identify, combining cerebellar incoordination and motor deficit on the same side of the body.
d. Pseudobulbar syndrome and lacunar state. These are due to the accumulation of lacunes in the white matter of the brain, particularly in the pyramidal tracts and basal ganglia especially of the striatum. This syndrome consists of spasmodic laughing and crying, primitive reflexes, dysarthria, and swallowing problems (WHO stroke report 1989).

1.1.7. Pathogenesis
Vascular disease of the brain takes four forms: thrombotic, embolic, lacunar, and hemorrhagic. Each has a different etiology, emphasis in its diagnostic workup, therapy, and prognosis

Thrombotic strokes
Thrombotic strokes are the most common, accounting for about 40% of all ischemic cerebrovascular disease. This type of stroke is usually due to atherosclerotic stenosis or occlusion of large blood vessel, especially the carotid or middle cerebral artery. The clinical effects of internal carotid stenosis, internal carotid occlusion, and middle cerebral artery stenosis may be quite similar, depending on the richness of collaterals, the speed of occlusion, and the individual vascular anatomy. Warning signs may precede the stroke; as many as one-half of patients with thrombotic strokes report previous TIAs.
Thrombotic strokes commonly occur at night. Because atherosclerosis generally invoives large vessels, the ischemia produced by thrombotic strokes tends to be extensive, and patients are often severely impaired.

Embolic Strokes:
Emboli cause 30% of strokes. Emboli strokes arise from platelets, cholesterol, fibrin, or other bits of homogeneous material breaking off from an arterial wall or from the heart. Most strokes occurring in the setting of myocardial infarction are the result of cardiac emboli. Cortical deficits including seizures, aphasia (dominant hemisphere), and neglect (nondominant hemisphere) are the hallmark of embolic strokes.

Lacunar Strokes:
They constitute approximately 20% of all strokes. They are very small infarctions, by most definitions less than 1 cm in size, that occur only where small perforating arterioles branch directly off large vessels. These small arterioles become thickened, hyalinized and thrombosed, resulting in small infarcts. These pathological changes are gradual and may produce symptoms resembling thrombosis, including a gradual onset and preceding TIAs. Since they occur in distinctive subcortical regions of the brain, lacunae produce characteristic clinical features. They do not cause aphasia, neglect, seizures, or other cortical symptoms. About 85% of patients experience a satisfactory recovery.

Hemorrhagic Stroke:
Intracerebral hemorrhage accounts for only 10% of all strokes. The onset is typically sudden accompanied by headache, nausea and vomiting, and a decreased level of consciousness. Hemorrhages occur usually at the same locations as lacunae. Subcortical deficits are thus most common, although they are more extensive than lacunar infarct. Hemiplegia, hemisensory loss and visual field defects are common, in addition to altered mental status. The prognosis of hemorrhagic stroke is poor, with an initial mortality rate of 50% to 70%. However, if the patient does recover, the blood may be reabsorbed leaving only mild deficits (Garrison & Rolak 1993).

1.1.8. Recovery From Stroke
Brunnstrom noted a specific sequence of events during recovery: a) Immediately following the acute episode, flaccidity is present and no movements of the limbs on the affected side can be initiated. b) As recovery begins, the basic limb synergies or some of their components may appear as associated reactions, or minimal voluntary movement responses may be present. Spasticity appears at this stage. c) The patient regains voluntary control over synergies: spasticity increases. d) Some movement patterns out of synergy are mastered, and spasticity begins to decline. e) If progress continues, more difficult movement combinations are learned as the basic synergies lose their dominance over voluntary motor acts. With the disappearance of spasticity, individual joint movements become possible and coordination approaches normal (Bach-y-Rita 1987).

The recovery process may stop at any stage; with the result that the patient may remain flaccid or synergy patterns may never yield to voluntary isolated movements.
Neurological and functional recovery occurs most rapidly in the first 1 to 3 months after a stroke, but some patients continue to progress after that time, especially with respect to language and visuospatial functions. In a community based study in New Zealand, Bonita et al found that 88% of all people registered as having stroke presented with a motor deficit. Most of the overall improvement occurred within the first month. Recovery of motor function was associated with the stroke severity but not with age or sex; patients with a mild motor deficit at onset were likely to recover their motor function than those with a severe stroke (Bonita et al 1988).

Jorgensen et al 1995 in Denmark, did a community based study to determine the time course of both functional and neurological recovery. They found that functional recovery was completed within 12.5 weeks from stroke onset in 95% of the patients. However 80% of the patients had reached their best ADL functions within 6 weeks from onset. The time course of functional recovery was strongly related to initial stroke severity. The time course of neurological recovery followed a pattern similar to that of functional recovery, but preceded functional recovery by 2 weeks on average.
he argument that neurological and functional recovery can continue beyond 3 to 6 months was supported by a recent study by Ferruci et al in which they followed up patients for 6 months after discharge from the hospital. Neuromuscular function, mobility, and activities of daily living continued to improve during follow-up, especially in the more severely impaired patients (Ferrucci et al 1993).

1.1.8.1. Factors That Influence Recovery Of Impaired Functions (WHO stroke report 1989):

- Site and size of the brain lesion is considered to be the single most important determinant of both the nature and severity of functional defect as well as the probability of functional recovery. A definite relation has been established between the severity of motor impairments, the location of a cerebral lesion, and the degree and rate of restoration of movement.
- The initial severity of the neurological deficit is an important predictor of the degree of recovery.
- The presence of other neurological impairments in addition to motor deficits can have an adverse effect on recovery. In a study mentioned in the WHO report, it was found that independent ambulation can be delayed if patients have sensory in addition to motor deficits, even more if patients have visual field defects.
- Age is a factor in recovery, but its significance is still controversial. Age is certainly a significant factor in the mental and social readaptation of patients.

- Cognition and higher mental functions are important in affecting the degree and rate of recovery especially of complex motor functions and the social readaptation of patients.
- It was found that stroke patients with right hemisphere lesions may have a poorer recovery of complex motor functions.
- There are several other factors that might affect the recovery of stroke patients such as spasticity, loss of bladder control, and hemianopsia. Concomitant cardiovascular disease can have a negative effect on the recovery process.
- There is no convincing evidence about the influence of social status including occupation, level of education and the role of the family on recovery from stroke.

1.1.9. Outcome of stroke

The Agency For Health Care and Research report on Post-Stroke Rehabilitation, in an analysis conducted on Medicare claims, found that 17% of patients who survived their strokes were admitted to a hospital-based inpatient rehabilitation program, 23% were treated in nursing facility and 40% received outpatient or home care rehabilitation services. A total of 73% received services in one or more of these types of settings (AHCPR 1995). It was estimated that for every 100 stroke patients who survive the acute phase of stroke, 10 will be without disability and return work, 40 mildly disabled, 40 severely disabled, and 10 institutionalized. In terms of mobility approximately four of every five stroke patients eventually regain the ability to walk independently with or without an assistive device. On the other hand, only two of three patients regain activities of daily living (ADL) independence (Stineman et al 1991). In a community based Danish study, they have found that 21% of the patients died during hospital stay, 15% were discharged to nursing homes and 64% were discharged to their homes (Jorgensen et al 1995).

1.1.10. Management of Stroke

Management of the different types of cerebrovascular disease may be divided into four parts:

1. Management of the acute phase:

Surgical revascularization of the occluded vessel should be done within 12 hours of stroke. However, patients are rarely brought early to the hospital and even if brought early, several hours may pass until the diagnosis is made. If the common or internal carotid artery has just become thrombosed, immediate surgical removal of the clot or the performance of a bypass procedure may restore function. In the acute phase urokinase or streptokinase to dissolve the clot can have a remedial effect if used in the early hours.

2. Measures to restore the circulation and arrest the pathological process

Once the stroke has developed, no therapy so far devised can restore the damaged cerebral tissue. However, measures are instituted at various stages of the process; when only transient ischemic attacks are occurring, at any point in the progression of a thrombosis in evolution, or when almost the full neurological deficit has appeared.

- Medical therapy: if the patient is comatose or stuporous, maintaining the vital signs and treating the patient on the lines of coma management are the important steps in management. Patients should remain horizontal in bed for the first few days, so as not to decrease the cerebral circulation. It is important that the blood pressure be maintained and treatment of the previously unappreciated hypertension should be deferred until later.
- Therapy of cerebral edema: in the first few days after cerebral infarction, cerebral edema may threaten life. Dexamethasone and mannitol could be beneficial in decreasing the edema.
- Anticoagulant Therapy: heparin and coumarin derivatives have been used extensively to prevent transient ischemic attacks and an impending stroke. They may also have an effect on a progressive thrombotic stroke. When to start treatment is still one of the unresolved question in using anticoagulants. However it is widely agreed that once the stroke is fully developed, administration of anticoagulants is of no value (Adams et al 1993). Before deciding to use anticoagulants, a definite diagnosis confirmed by CT-scan is very important in ruling out intracerebral hemorrhage; to anticoagulate would be disastrous.
- Antiplatelet Drugs: Aspirin has proved to be the most useful drug in the prevention of thrombotic and embolic stroke. The acetyl moiety of aspirin combines with the platelet membrane and inhibits platelet cyclo-oxygenase, thus preventing the production of thromboxane (A2), a vasoconstricting prostaglandin, and also prostacyclin, a vasodilating prostaglandin. A platelet aggregate inhibitor ticlopidine can also be used.
- Surgery: Two studies, the North American Symptomatic Carotid Endarterectomy Trial and the European Carotid Surgery Trial, have extensively investigated the use of carotid endarterectomy. The conclusion in these studies is that for lesions causing severe degrees of stenosis (>70 percent) carotid endarterectomy is highly effective in preventing ipsilateral hemispherical strokes. In the case of intracerebral hemorrhage surgical removal of the clot in the acute stage, either by evacuation or aspiration can be lifesaving.

3. Measures to prevent further strokes and progression of vascular disease: The primary objective of in the treatment of stroke is prevention so every effort should be directed in controlling the modifiable risk factors mentioned in the risk factors section.

4. Rehabilitation After Stroke

Patients who survive the acute stage of stroke may have major neurological and functional deficits which require rehabilitation. Rehabilitation is defined as the restoration of disabled individuals to their greatest possible level of physical, mental, and social function. Rehabilitation is both a philosophy and a set of tasks; a rehabilitation program is comparable to school in which the patient is provided an opportunity for instruction, support, protected practice, education, reassurance, direct assistance, and feedback (AHCPR 1995). The patient and family are involved in setting goals and planning and implementing treatments, and systematic withdrawal of assistance and return of control to the patient. Rehabilitation is done *with* the patient rather than *to* the patient. The WHO report on stroke has summarized the aims of rehabilitation as:

- improvement of motor, speech, cognitive and other impaired functions.
- mental and social readaptation of patients to restore functional autonomy, social activity, and interpersonal relationships.
- where possible, a return to the activities of daily living.

Brandstater and Basmajian 1987 and AHCPR clinical guidelines 1995 have identified the common features of comprehensive stroke rehabilitation programs:

- Commitment to continuity of care from the acute phase through to discharge and follow-up, and leadership to the team.
- Use of an interdisciplinary team approach with a team of professionals knowledgeable and experienced in stroke rehabilitation.
- The prevention, recognition, and treatment of co-morbid illnesses and intercurrent medical complications.
- Early initiation of goal directed treatment that takes maximal advantage of the patient's abilities and minimizes disabilities.
- Emphasis on skills development and functional enhancement through training, demonstration, supervision, practice and appropriate feedback.
- Systematic assessment of the patient's progress during rehabilitation, with adjustment of treatment to maximize benefits.
- Emphasis on patient and family/caregiver education.
- Attention to psychological and social issues affecting both the patient and family/caregiver.
- Early and comprehensive discharge planning aimed at a smooth transition to the community, and at continuity of care to promote social reintegration and resumption of roles in the home, family, recreational, and vocational domains.

Rehabilitation of stroke patients is an important part of the management of stroke. As discussed above the sequelae of stroke present themselves with different degrees of neurologic, cognitive, and behavioral disorders. Within a few hours to a few weeks, stroke patients may show complete reversal of neurological symptoms or there may be significant residual deficits.

Rehabilitation is intended to assist in and accelerate the recovery of impaired function.

The same report summarizes the basic principles of rehabilitation as: carefully select the patient, begin early, be systematic, build up in stages and include the types of rehabilitation treatment specific to the deficit.

Since survivors of stroke constitute the largest group of patients receiving rehabilitation services in the US, research in the cost effectiveness of rehabilitation has been the topic of many clinical trials. Ottenbacher et al 1993, assessed 36 clinical trials meeting selected criteria by the methods of meta-analysis. They concluded that programs of focused stroke rehabilitation may improve functional performance for some patients who have experienced a stroke. They noted that the improvement in performance appears related to the early initiation of treatment, but not to the duration of intervention. The importance of further research in evaluating the different issues was emphasized. Ernst 1990, in his review of stroke rehabilitation and physiotherapy literature found that the majority of hard evidence does imply that stroke patients benefit from rehabilitation with physiotherapy. The benefit may be statistically small, but for a given individual, it could mean the difference between living at home or in an institution.

Jorgensen et al (1995), in their community based study evaluated the benefits obtained from rehabilitation in stroke patients and found that organized stroke rehabilitation treatment may be offered to a wider spectrum of stroke patients than previously given. The reduction in post-rehabilitation disability and the discharge rate to nursing homes reflect the need for post-rehabilitation services in stroke patients. Jeffrey et al 1995, in their recent review of stroke rehabilitation concluded that ample evidence exists that stroke rehabilitation improves outcome in patients with moderate neurologic deficits after stroke. In contrast to Ottenbacher et al results they found that prolonged rehabilitation could significantly improve outcome.

1.1.10.1. Managing The Rehabilitation Process

Stroke rehabilitation begins during the acute hospitalization and continues till discharge from the rehabilitation facility and re-entry to the society. The different medical and social issues addressed in stroke rehabilitation and their management are discussed in more detail in the clinical guidelines of Post Stroke Rehabilitation (AHCPR 1995).

1.1.11 Gait Changes In Stroke

In neurologically intact subjects, gait is a skill that is mastered in a relatively uniform way. The three functional goals of human ambulation are as follows: 1) to move from one place to another, 2) to move safely, and 3) to move efficiently.

The gait of the hemiplegic patient is frequently not safe or energy efficient. Impaired balance, sensory deficits, and foot drag all contribute to loss of balance, falls, and increased anxiety regarding ambulation.

Stroke patients usually have impaired normal mechanisms of selective control, proprioception, and body image. They also have disturbed muscle action manifested as exaggerated locomotor patterns, spasticity, postural reflexes and contractures due to muscle weakness (Perry & Montgomery 1987).

a) Selective control: the loss of selective control presents in a clinical picture of flaccid paralysis. An example is when weight bearing is attempted by the patient, but the whole limb collapses because of quadriceps weakness. During swing the most common signs of impaired selective control are foot drop, toe drag, or inability to advance the limb. Loss of selective control commonly is replaced by more primitive sources of muscle control as showing locomotor patterns, spasticity and postural reflexes.

b) Primitive locomotor control: the stroke patient can initiate either mass extension or flexion as an alternate voluntary muscle control. The muscles of a synergistic group begin and terminate their actions simultaneously. In stance phase when the knee is extended the ankle also plantarflexes and the hip extensors contract. The flexor pattern consists of the patient flexing the hip to take a step, the knee also flexes and the ankle dorsiflexes. However only the tibialis anterior participates in the dorsiflexion with the foot being inverted. This may preposition the foot in an unsafe loading posture. The gastrocnemius-soleus muscle is the strongest plantar flexor. The soleus muscle in addition to its plantarflexion action has a strong inversion action.
When it contracts at the onset of stance, as part of the primitive extensor pattern, the foot is poorly positioned for weight bearing. The toe flexor muscle action is the next most common foot muscle participating in the extensor pattern, which is evidenced by the clawing of the toes. This causes pain and limits weight bearing.

c) Postural reflexes: the limb or body position changes may alter muscle tone. In the standing position, the intensity of extensor muscle action may be more than double that elicited with the patient lying.

- Spasticity: is the increase in muscle tone found in patients with stroke or upper motor neuron lesion.
- Contracture; muscle weakness and fibrous tissue changes accompanying prolonged bed rest in stroke patients lead to increased resistance to stretch. This is persistent throughout the gait cycle. If early range of motion exercises are not provided the patients will have a corresponding degree of contracture that will limit their mobility in the future.

General gait changes have been demonstrated in stroke patients which include a decrease in walking velocity with a shorter stride length, shorter stance phase, and increased swing time for the involved limb. A decrease in weight bearing on the involved limb has been noted, as well as a decrease in single support time. The unaffected limb has increased stance time. Stance phase abnormalities include:

- Forefoot first or flat foot initial contact rather than heel first; in addition ankle inversion may occur with the lateral border of the foot contacting the ground first.
- Incomplete knee extension may be noted. Hyperextension of the knee is common, with continued equinovarus deformity of the ankle during mid-stance.
- During terminal stance, heel-off can occur early or late, and the pelvis may drop on the contralateral side.

Swing phase abnormalities include:

- During the initial swing, inadequate hip and knee flexion may result in toe drag.
- During mid-swing, a major problem is insufficient dorsiflexion.
- During terminal swing, the inability to coordinate hip flexion and knee extension produces a shortened step length, which may be complicated by insufficient ankle dorsiflexion.

From a functional perspective, one can categorize gait deficiencies on the basis of their timing with respect to the gait cycle. During stance phase an abnormal base of support and limb instability may make walking unsafe, energy inefficient, and possibly painful. Inadequate limb clearance and limb advancement during the swing phase interfere with safety and energy efficiency. In addition to spasticity or weakness as the main causes of limb deformities that interfere with walking, the clinician should be aware that there are reasons such as joint contractures, new bone formation, undiagnosed fractures and reflex sympathetic dystrophy may contribute to gait dysfunction.

To identify and evaluate the gait problems of stroke patients, the clinician must be able to understand *what* the problem is, *where* and *when* it is present, and why it occurs.

a) *Abnormal base of support*: the lack of adequate base of support results in instability of the whole body. Some authors claim that abnormal ankle-foot posture is the main reason of the whole body instability (Esquenzai et al 1991, 1995). Equinovarus deformity is the most common pathological lower limb posture seen in the hemiplegic patient. This posture results in an unstable base of support. The contact occurs with forefoot first and weight bearing on the lateral border of the foot in stance phase. Limitation in dorsiflexion prevents

forward progression of the tibia over the stationary foot, causing knee hyperextension and interference with terminal stance and preswing where lack of a propulsive phase is noted.

Dynamic poly-EMG recordings demonstrated that the most frequent cause of plantarflexion are the prolonged activation of gastrocnemius-soleus complex and the long toe flexors (Esquenazi et al 1995). Inversion is the result of the abnormal activity of tibialis posterior and/or anterior in combination with the gastrocnemius-soleus group and the extensor hallucis longus. In some cases the lack of counterbalancing activity by the peroneal group may be encountered.

b) *Abnormal limb instability*: which is manifested as knee collapse or hyperextension. This problem is especially evident in the early phase of recovery. Knee hyperextension present during the stance phase is the result of spasticity of the ankle plantar flexors, a plantar flexion contracture, or less likely in the stroke patients, compensation for knee weakness. Hip flexion during stance phase is a less common gait abnormality.

c) *Limb clearance*: During the swing phase limb clearance and advancement occur. The advancement of the limb in stroke patients is compromised when limb clearance is inadequate. The most common consequences for inadequate limb clearance in stroke patients are lack of adequate hip flexion, knee flexion, and ankle dorsiflexion (Esquenazi et al 1995).

- Stiff knee gait pattern is most commonly seen in the spastic hemiplegic patient. The inability to flex the knee creates a need for more energy to initiate the swing of the invoived limb. This requires the patient to utilize ipsilateral hip and trunk and contralateral limb compensatory mechanisms. A possible explanation of this gait abnormality, as found using dynamic poly-EMG, is increased activities in the quadriceps muscles as a group with or without hamstring co-contraction. Lack of momentum because of decreased walking speed is another possible cause of this problem.
- Inadequate hip flexion is also a cause of abnormal limb clearance. This gait abnormality prevents the physiological shortening of the limb producing toe drag in the swing phase. Compensatory techniques such as hip external rotation and adduction are attempted by the patient.
- Increased hip adduction can interfere with ipsilateral and contralateral limb advancement and other activities of daily living. It may cause balance problems due to a narrow base of support. However many hemiplegics use hip adduction to compensate for hip flexion in limb advancement.
- In the late swing or early stance phases, hemiplegic patients may have incomplete knee extension resulting from hamstring spasticity. This results in a shortened step length as the knee is flexed and the foot is unable to " reach " the ground.

- Pelvic retraction of the involved side during a gait cycle interferes with limb advancement, resulting in a shortened step.
- Another gait abnormality is inadequate ankle dorsiflexion during mid-swing phase, leading to typical foot drop. Plantar flexion contractures which are static contractures create the same foot posture in mid-swing (Perry & Montgomery 1987).

Winters et al 1987, have identified four gait patterns in hemiplegic patients; group I with the foot drop in the swing phase being the primary gait anomaly, group II had a tight heel as well as foot drop, group III had restricted knee motion in addition to the equinus deformity, group IV had, in addition restricted motion of the hip.

1.1.11 1. Gait Analysis Study

When a stroke patient presents to the clinician with a gait dysfunction for management, gait analysis is used to better understand their anomaly. It is indicated to determine deficiencies, guide therapy, and monitor progress. The goals of gait analysis usually fall under five categories (Oatis 1995):
1. To describe the difference between a patient's performance and a normal subject's performance.
2. To classify the severity of a disability.
3. To determine the efficacy of intervention.
4. To enhance the performance.
5. To identify the mechanisms causing the gait dysfunction.

Gait laboratories yield information which is comprehensive, but often difficult to correlate clinically, hence decreasing their practical application (von Schoeder et al 1995). The study of gait had been attempted in the past (Marks 1953) using simple photographic methods. Recently several gait analysis methods have developed. The variables that can be recorded can be grouped into the following:

a) Spatial and temporal measures: In order to characterize gait, some basic output variables that concern the temporospatial structure and sequencing of stance and swing phases can be measured. These include walking velocity, stance and swing times for each side as well as stride length and stride duration. Comparison of right and left sides can be used as well. There have been many studies assessing these different variables and their relation to the outcome measures. Holden et al (1984), found that velocity, cadence, step length, stride length, and stride length divided by lower extremity length appear to be excellent tools for assessing physical therapy outcomes in hemiplegics because they are highly reliable and relate significantly to function status. Holden et al (1986), evaluated these variables and concluded that velocity appears to be a composite

measure of other variables, correlates well with energy consumption and is easiest to measure. However, they found that the use of an orthosis did not appear to influence temporo-spatial values. Brandstater et al (1983), analyzed the different temporal gait measures with respect to clinical status and found walking speed and symmetry of the swing phases were significantly related to motor recovery. Speed becomes progressively slower as the motor deficit becomes more severe. The test-retest reliability of velocity and cadence measurements of hemiparetic patients is very high as reported by Bohannan (1987). Also these variables are significantly correlated with one another which provides evidence that the measures are not independent of one another as indicators of ambulatory status (Bohannan 1987). Bohannan (1992), in another study found that stroke patients can increase their walking speed significantly above the level they find comfortable Although symmetry of gait has been considered by some investigators as an important temporospatial measurement, others question this issue. Tyson (1994), found that symmetry parameters were not related to the severity of hemiplegia or gait performance and different walking conditions had little influence on the symmetry of temporospatial factors of the stride. Wall et al (1986) in assessing the temporal gait asymmetries in stroke patients found that the extent and patterns of these asymmetries varied with respect to gait cycle despite the relative functional homogeneity

b) Kinematics: provides a description of movements without regard to the forces generating them. Modern systems include the use of accelerometers, goniometers, and high speed video/film recording.

c) Kinetics: deals with the forces, moments, and mechanical energies that develop during the course of walking. This needs more complex and expensive equipment and analysis.

d) Electromyographic patterns in human gait: The EMG signal can be used as an indication of the neurologic control of muscle activation. A particular muscle may be either over- or underactive during a given segment of the cycle. After these observations are made they should be carefully correlated with patient kinematics (Esquinzi et al 1991).

e) Miscellaneous: Several other methods have been suggested but not widely used. Visual assessment of the hemiplegic gait using a detailed form showed reliability in its results (Hughes 1994). There are systems developed to assess gait especially foot drop and inversion, but still on experimental basis (Granat MH et al 1995)

1.1.12. Orthotics In Stroke

An orthosis is defined as an externally applied device used to modify structural and functional characteristics of the neuromuscular system in order to support, correct, or protect the body part. The role of lower extremity orthotic devices in hemiplegic patients includes the following:

- stabilization of an unstable joint
- to complement activity of a weak muscle
- to prevent contractures
- to enhance sensory feedback in patients with impaired proprioceptive sense in the lower extremity.

The decision to prescribe a proper orthosis is a team work comprising the following: physiatrist, certified orthotist, and physiotherapist.

Before describing a lower extremity orthosis, a proper clinical examination of the hip, knee and ankle joints for range of motion and determining the presence or absence of contractures is done. Knee and ankle-foot stability is tested, and muscle tone is examined by passive movement. Muscle strength is tested. Test of sensory functions as touch, pinprick, vibration sense, and position sense is important. Ataxia is not an indication for a brace.

An ankle foot orthosis (AFO) is the most commonly used orthosis in stroke patients. Lehmann et al (1979, 1987) described many types of AFOs. Up until 1967 the AFOs were made of metal and leather. The basic design was double metal bars which were attached externally to a heavy shoe. Later the plastic AFO was introduced. An AFO helps some of the stroke gait deficits. It was also found that oxygen consumption related to gait in hemiparetics is 64% higher than that of normal persons. It was reduced with use of an orthosis, but the choice of the brace did not make any difference (Corcoran et al 1970). It was noted that there was a 20% decline in the prescription of lower extremity orthosis of all kinds in the years 1966-1977 (Offir et al 1980).

AFOs tend to limit plantar flexion with the result of knee instability during stance. In helping to alleviate the toe drag, knee stability can be compromised. There is a trade-off between knee stability and the amount of toe pickup required during the swing phase. The more dorsiflexion is given for toe pickup the less knee stability. AFOs allow safe ambulation by improving mediolateral instability in stance phase and toe clearance in swing phase. The main benefits of AFOs may be to increase walking speed and normalize the heel-strike. Experience with AFOs revealed problems in the lack of total contact fit, poor ankle position and pressure sores. Anterior AFOs have been tried and given comparable results to the posterior plastic ones (Esquenazi et al 1991, Dittemer et al 1993).

The use of knee-ankle-foot orthoses (KAFO) by stroke patients requires a large energy expenditure. Its use is usually limited to the early recovery phases when the patients ambulation is limited. The principal objective in using the KAFO is to support and control the patient's knee and ankle simultaneously. It is usually replaced with an AFO later in the rehabilitation program (Dittemer et al 1993).

1.2. FUNCTIONAL ELECTRICAL STIMULATION

Functional electrical stimulation is the application of electrical current to elicit a muscle contraction. The use of functional electrical stimulation in rehabilitation medicine has grown significantly in recent years. In this section, the clinical applications of FES in general will be discussed with special emphasis on its use in stroke patients.

1.2.1. Historical Perspective:

The earliest use of electric "devices " in medicine was described by Hippocrates in about 420 B.C. He recommended the use of torpedo fish, which produces electric charge, to asthmatic patients. Scribonius Largus, a Roman physician, used the torpedo fish to treat painful conditions. The first recorded medical treatment using electrical stimulation dates back to 1744 in Germany. Christian Gottlieb Kratzenstein claimed that by applying electricity for less than one quarter of an hour, he restored function to a paralyzed small finger of a female (De Vahl 1992).

The first scientific paper which describes and discusses the application of electricity to muscles was published by Luigi Galvani "De Vibrius Electicitatis, In Motu Musculari Commentarius which appeared on March 27,1791 in the Proceedings of the Bologna Academy and Institute of Sciences and Arts in Italy. However his explanation was that the muscle had an inherent "animal electricity". Count Alessandro Volta, who is one of the principle discoverers of electricity in 1793 attributed the source of electricity to the metal rod used in the experiment, rather than the animal's muscle. However, Galvani understood that in the live body, muscle contractions are due to some internal electrical process. The German physiologist Grapengiesser (1801) observed that contractions were short-time phenomena that closely followed the time instance of connecting or of disconnecting the electricity and did not occur during steady state. He suggested that muscle contraction requires short-duration pulses of electricity. In 1831, Michael Faraday invented an electrical generator that produced an alternating current when a metal is rotated in a magnetic field and the current was called "faradic current". By the middle of nineteenth century, D.B. Duchenne was interested in the physiology underlying electrotherapy. Often called the "father of electrotherapy", he is known for identification of motor points and muscle actions.

Electrodiagnostic devices were introduced in the mid-1800s. Investigators noted that paralyzed muscle responded to galvanic but not faradic current. Once the battery and induction coil were invented and readily available, the golden age of medical electricity began. Although electric devices were commonly used by physicians, they were cumbersome. In some of these devices, the physician by handling a sponge electrode can monitor the proper dosage of the current by his response to the current passing through him! Electrodes were typically made of brass or chromeplated brass covered with felt or sponge. Water was the conductive medium. During World War II, treatment of peripheral injuries grew with the development of clinical stimulators able to generate stimuli that can excite both denervated and partially denervated muscles (DeVahl 1992, Graupe et al 1994).

The concept of improving walking using FES was first introduced in 1960 by Liberson et al in the Hines VA hospital in Chicago (Liberson et al 1960). This is the first scientifically documented attempt to provide functional movement as a rehabilitative method for persons suffering from paralysis of certain limbs, and this marked the start of research and development to provide FES assistance as a rehabilitative and functional method and device. All the other FES developments of locomotion systems were created, started and influenced by the developmental events and aspects of the Peroneal system functional enhancement (Kralj et al 1995). The original design of the foot-drop stimulator was patented in 1967 (Offner et al 1967). Commercialization started but was soon stopped. After that many centers in Europe and United States used the FES systems but they did not prove satisfactory in terms of clinical usefulness, adequate functioning, cost effectiveness, and practicality. These findings led to a diminished interest in FES after a few years (Rodgers 1995).

The use of FES systems in spinal cord injured patients was first pioneered by the work of Kralj and Vodovnik in Ljubljana, Slovenia. This group presented results with implanted electrodes to assist in standing and swing-to and swing-through crutch supported gait. Widespread public awareness of FES research originated in the early 1980s, with the media reports surrounding the FES aided standing and gait work by Petrofsky. This led several companies to invest in FES technology and bring it to the consumer. However, this also led to misleading expectations of the state of FES research and its practical use in the future (Durfee 1992). In the late 1980s and 1990s there has been more research in the field of FES especially in restoration of gait in patients using FES. Also the technology of FES has developed tremendously in the past few years. In 1994 the FDA approved the use of The Parastep FES system for the standing and walking of spinal cord injured patients (Graupe et al 1994).

The clinical applications and the number of patients using FES today for movement restoration is rather low considering the 30 years of extensive

research, developments and investments (Kralj et al 1995). With the progress of new technologies, FES remains an exciting field that requires more research and development and is attracting people involved in rehabilitation medicine (Dittmer et al 1993, Andrews et al 1994). In this study only FES applications in Stroke mobility and related issues will be discussed

1.2.2. Clinical Applications

During the last 10 years, research and development of locomotion in hemiplegia has not been a top priority in the programs of national agencies responsible for funding this field (Stanic et al 1991, Kralj et al 1993).

FES, as mentioned above, has been in limited use in stroke patients both for upper and lower extremities. The most extensive study was done in Ljubljana, evaluating 2500 hemiplegic patients examined for FES during the last 10 years. According to their criteria, up to 63% of annual cases are candidates for an FES-based therapeutic locomotion rehabilitation program. Single channel users to correct equinovarus constituted 60%, 30% used dual or even 3-channel stimulation. Only 10% of patients were involved in multichannel (4,6 or even 8 channels) FES systems (Kralj et al 1993). There are no international statistics on the number of stroke patients using FES.

1.2.2.1 Selection Of Patients For FES Program

General selection criteria have been developed. In the experience of the Ljubljana group, the criteria for surface and for some implanted stimulation are (Stanic et al 1991):

1) compensated cardiovascular system
2) intact skin
3) adequate range of motion
4) no severe lesion of peripheral nerve and well preserved muscle contractility
5) no hypersensitivity to stimulation
6) adequate psychological status and ability to communicate and cooperate with the rehabilitation program.
7) adequate motivation

Additional criteria for implantable stimulation are as follows:

1) no further improvement of motor function can be expected from the patient using the conventional methods, including surface FES.
2) a good correction of gait pattern has already been obtained by the previous application of surface FES.
3) the encumbrance level with the surface FES system limits its use in activities of daily living.
4) surface FES cannot produce a sufficiently strong response or the muscle required can not be stimulated from the surface e.g. iliopsoas.

1.2.2.2. Electrode Systems

Electrodes represent one of the most important issues in functional electrical stimulation. Early electrodes were made from conductive metal or a sponge moistened with water. Carbon-impregnated silicon-rubber electrodes have replaced metal in most cases and are available in a range of shapes and sizes. There are various commercially available electrodes in the market today.

Effective electrode systems should meet the following criteria (Ljubljana Report 1971, Popovic 1992, De Vahl 1992):

1. Promote low skin electrode impedance.
2. Conduct current uniformly.
3. Maintain uniform contact with the skin.
4. Allow desired movement of body parts.
5. Be cost effective.

There are several types in the market with a conductive interface to transmit the current from the electrode to patients skin. Conductive gel, karaya pad and synthetic polymer gel are examples of the interfaces used today.

Electrode size is an important feature of electrodes. The optimal size depends on the desired muscle response, the size of the target tissue, and the electrode placement chosen. In general, electrodes should be no smaller than the size of a dime if used for prolonged stimulation periods to avoid concentration of the current, sensory discomfort and possible burns (Balmaseda et al 1987, De Vahl 1992).

Placement of the active electrodes should be avoided over scar tissue and bony prominences because impedance is increased compared to normal skin and muscle. Close placing of the electrodes encourages superficial passage of current, whereas increased spacing of electrodes further apart promotes deeper penetration of current. Positioning the reference electrode close to the active electrode may limit the current penetration. The negative electrode (cathode) is often used to evoke contraction and is termed the active electrode and the other is the inactive reference electrode (Popovic 1992, Ljubljana Report 1971, Baker et al 1993).

1.2.3. Patient Safety Measures

Like any therapeutic modality, FES should be applied with sound clinical judgment. There are, however certain precautions which should be considered prior to FES application especially in stroke patients since the majority have medical problems (De Vahl 1992, Baker et al 1993, Ljubljana report 1971):

1. Patients with pacemakers: FES applied at frequencies of greater than 30 Hz can cause reversion of a demand type pacing mode to an asynchronous mode. Therefore the use of FES with patients who have a demand type cardiac pacemakers is not recommended, except under closely monitored conditions.
2. FES should be applied cautiously in patients with known or suspected cardiac conditions such as arrhythmias or conduction defects. All cardiac patients should be closely monitored for signs of dizziness, shortness of breath, palpitations or syncope, during and immediately following application of FES.
3. The effect of FES on fetal development and health has not been defined. Therefore, the application of FES to the abdominal perineal or lumbar region during pregnancy is not recommended.
4. Electrode placement must be considered as a factor in patient's safety.
   - avoid placement of electrodes on anterior neck which might deliver currents to vagus or phrenic nerve,
   - avoid placement close to incision site,
   - avoid placement on scar tissue because scar tissue has a higher impedance,
   - placement over significant adipose tissue is not contraindicated but may prohibit the stimulation program from being effective, since adipose tissue impedes current flow.
5. Skin irritation may be caused by electrical, chemical, or mechanical factors. To decrease the possibility of irritation from electrical factors, a larger stimulating surface should be used. Uniform contact with a conducting medium should be maintained between the electrode and skin. Chemical irritation is caused by an allergy from the conductive gel or adhesive material. Selecting a different type of electrode might solve this problem given the wide variety of commercial electrodes available. Slight redness following a stimulation session will usually dissipate within 30-60 minutes. If it persists, relocation of the electrodes should be tried first. When it continues, minimal stimulus parameters should be tried. In the occasional patient where it persists, the patient is not an appropriate candidate for FES.
6. Mechanical irritation caused by shear force between skin and adhesive material during movement. Placing the limb in the position of maximum skin stretch when applying the electrodes will decrease the incidence of irritation.
7. Patient acceptance and willingness to participate in any FES program is of prime importance. Most patients will find the sensation of stimulation unusual at first, but most will come to accept it with use. A training program may help patients to accept the stimulation. An occasional patient will not tolerate the sensation caused by FES. A more detailed study of discomfort and FES is discussed in a later section.

1.2.4 Clinical Indications Of FES In Stroke Patients

The following indications for including FES in physiotherapy program have been developed (Stanic et al 1991, Baker et al 1993):

1) to replace central control of movements with an outside auxiliary control.
2) to achieve a functional selective response of the stimulated muscle or muscle groups.
3) to reduce or eliminate anomalies of gait by facilitation and reeducation of voluntary motor function
4) orthotic substitution
5) maintenance or increase in the range of motion and prevention of contractures
6) to reduce spasticity
7) to achieve better circulation and decrease edema.

The Food Drug Administration has approved neuromuscular electrical stimulation devices as safe and effective for the following application (De Vahl 1992):

a) treatment of disuse atrophy
b) increase and maintenance of range of motion
c) muscle re-education and facilitation

In order to select and screen patients who can use FES the following testing procedures are done :

a. general medical, neurological, psychiatric, and socioeconomic evaluation.
b. specific testing of range of motion (ROM), residual motor function, proprioception, gait and functional responses to stimulation, and
c. testing of activities of daily living (ADL).

1.2.5. Rehabilitation Goals And FES In Stroke Patients

The use of Therapeutic and Functional Electrical Stimulation can accomplish the following rehabilitation goals in stroke patients:

I. Increase Passive ROM:

Electric stimulation applied to antagonist muscles of the shortened group at the end of the available joint ROM can be used to provide stretch. However some joints like the hip and shoulder can not be effectively moved through full ROM with the use of FES because of the inability of the stimulation to overcome the weight of the limb. It can also be used along with other modalities like stretching, bracing, or splinting to provide elongation of musculotendinous unit in soft tissue tightness.

II. Glenohumeral Joint Reduction:

The conventional management of glenohumeral subluxation in the hemiparetic patient includes positioning, upper extremity orthotic devices, electrical

stimulation to the supraspinatus and posterior deltoid muscle to provide glenohumeral approximation. FES serves to reduce the subluxation proximally without interfering with the distal limb functions. Wearing a conventional upper extremity orthosis 24 hours a day is impractical and uncomfortable. Proper positioning of glenohumeral joint can be provided by using FES for increasingly long periods as tolerance to the stimulation increases.

III. Edema reduction:
The hemiparetic patient is often incapable of isolated dorsiflexion and/or plantarflexion of the affected ankle. FES can elicit cyclic contraction of the dorsiflexors and/or plantarflexors of hemiparetic patients to augment venous return and reduce dependent edema. This method has the advantage of activating appropriate muscles in the absence of volitional activation. It can be combined with positioning and compression for a more complete treatment program.

IV- Increased Volitional Activation and Control of Paralyzed Limb Musculature by Neuromuscular Re-education:
FES, biofeedback, and FES in combination with biofeedback can all be used to enhance neuromuscular re-education. FES can produce motor activity of a quality the patients are incapable of voluntarily producing. The FES exercise may take the simple form of eliciting a strong contraction of a minimally active muscle. The therapist working with the patients on neuromuscular control can use a hand-held remote switch to provide the FES muscle contraction synchronized in time with the patient's own attempts to activate the muscle.

FES can be used to elicit a strong muscle contraction at the time of a functional activity, when the affected muscle would normally be active e.g. to facilitate the hip abductors during weight bearing activities on the affected side. FES can also be used to provide a sensory "reminder" to strong but inappropriately inactive muscle during an activity when that muscle will normally be active, similar to the use of tapping, a conventional physiotherapy technique..

It is also beneficial to facilitate an active movement deviating from synergy which the patient is unable to perform independently e.g. hemiparetic patient who has some active hip flexion and knee extension but can not combine them to achieve straight leg raising. In this case FES can be applied to the quadriceps muscle. Electrically stimulated muscle contraction can be used to position an extremity for activity, in much the same way that a device like an air splint is used (Packman 1992).

Combination of electric stimulation and biofeedback can be used to facilitate neuromuscular re-education. Cozean et al 1988, studied the efficacy of FES and biofeedback treatment of gait dysfunction in patients with hemiplegia after stroke.

The combined method resulted in improvements in the minimum flexion angles of both knee and ankle during the swing phase that are statistically significant. Velocity of gait, cycle time, and symmetry of stance phases also improved.

V - Increasing Strength:
Isometric or isotonic contractions can be elicited with a single or dual channel FES devices. It can be used in conjunction with isokinetic devices in order to provide strength training. FES, active exercise or a combination of these approaches is a reasonable treatment course for more superficial muscle groups (Delitto et al 1990).

Advantages of FES for muscle strengthening are: First, attention span is not a limitation as it is with active exercise. Secondly is the availability of a multichannel stimulator that can simultaneously strengthen more than one muscle group. A major disadvantage is the rapid onset of muscle fatigue associated with electrically induced contractions. Care must be taken to optimize stimulation parameters and minimize fatigue whenever a program of FES involving a repetitive contraction is planned .

VI - Tone Reduction:
In addition to the conventional means of dealing with spasticity as icing, gentle stroking, medication, FES may be applied to the spastic muscle or its antagonist. It is advantageous to use a combination of methods during the treatment course to decrease tone (Packman 1992). Stefanovska et al (1988, 1991), studied the effect of FES use in 8 hemiplegic patients. Long term use of FES resulted in decrease of tonic spasticity in both ankle joint antagonistic muscle groups. Matsushita et al (1992), studied the effect of FES on the spasticity of 10 upper motor neuron lesion (8 stroke & 2 spinal cord injury) patients. A decrease in the spasticity was observed.

VII - Management & Enhancement of Sensory Awareness:
In the treatment of hemiparetic patient with decreased sensation, the clinician is constantly trying to increase the sensory input to the CNS through facilitation techniques like tapping, patting and so on. Also, to facilitate the patient's use of intact sensory pathways which are intact in order to compensate for areas of deficit. Both FES and EMG biofeedback are useful adjuncts to these treatment goals. It is thought that these afferent inputs will enhance the redevelopment of effective sensory pathways from the area of stimulation (Takebe et al 1976, Crone et al 1994).

VIII - Normalizing Gait Patterns:
The conventional management of gait deviations takes numerous forms including pregait mat activities, exercise, facilitation, component activities in the upright

position, orthotic application, and progressive gait training in the parallel bars and in some cases augmenting it with devices. FES as an orthotic substitute and EMG biofeedback may also be considered gait training options.

FES with hand or heel switch timed to coincide with the patient's individual gait pattern can be useful adjunct to many gait training programs. There are gait deviations that can not be effectively managed through the use of FES. Deviations of gait like pelvic retraction and depressed hip flexion with external rotation and adduction used to advance the involved extremity are not well suited to the use of FES because the affected muscles are too deep to be reached with surface electrodes.

In case of insufficient knee flexion for swing, neither conventional bracing nor FES applied as an orthotic substitute are suitable choices for management. If the withdrawal reflex is used, knee flexion can be achieved with FES. Hamstring stimulation has been tried as part of multichannel stimulation FES to provide knee flexion. A KAFO is not capable of providing a knee-flexion assistance. Knee flexion for limb clearance during swing is for the most part passively provided as a result of momentum generated by hip flexion (Packman et al 1992).

1.2.6. Literature Review

This literature review will cover the relevant literature of the application of FES in patients with strokes. The largest assessment of FES use in stroke patients was done in Ljubljana by Kralj et al (1995). They reported that between 1980-1990, 1575 of 2500 hemiplegic patients were FES treated and 60% utilized one channel FES, 30% two channel FES systems and only 10% multichannel. This literature review is subdivided into 3 sections with literature relevant to foot-drop stimulator, dual channel and multichannel FES stimulators.

1.2.6.1. Foot Drop Stimulators (Peroneal Brace)

The rehabilitation of hemiplegic patients using FES was first introduced by Liberson et al (1961). The stimulus was applied to the Common Peroneal nerve to stimulate the pretibial muscles with the use of a heel switch. When the heel is lifted from the floor the heel switch sends a signal to the stimulator to contract the muscles. Later developments were based on this basic idea. Reviewing the literature there are several early patented electrical stimulation devices with the basic idea of Peroneal nerve stimulation; Giaimo CV (1956), Keegan JE (1963), and Offner FF (1967). Most of the developed FES systems were inspired and started from the idea of the simple foot-drop stimulator (Kralj et al 1995).

In a series of studies done by the Ljubljana group and published as a report, different modifications of the foot drop stimulators were developed. Many versions of the walking rate dependent electronic foot-drop stimulator were

developed (Kralj 1971). The implantable radiofrequency foot-drop stimulator emerged which consists of a shoe insole containing radiofrequency switch and an implantable receiver/stimulator. The advantage of these radiofrequency stimulators is that no connection wires are needed (Vodovnik 1971). The myoelectrically triggered foot-drop stimulator which is triggered by the muscles of the back was developed later. All these devices remained experimental and with very limited use. However, these early studies founded the basis of most of the research that is going on now. With the advance of technology and the more scientific and clinical approach to the assessment of the use of FES, clinical use seems closer and more practical.

Several commercial Peroneal stimulators appeared in the market in the seventies and studies assessing these stimulators were published. Takebe et al 1975, tested the Peroneal stimulator on 9 hemiplegics, only 3 patients who tolerated using the stimulator and showed improvement in function in terms of muscle force, continued using it. The problems were discomfort, difficulty in locating the correct stimulation site and the problems encountered using the device on stairs. Using Peroneal stimulator for biofeedback treatment of foot-drop after stroke was tested in several studies by the same author and others (Takebe et al 1975, Takebe et al 1976, Basmajian et al 1975).

Merletti et al (1979) studied the use of foot-drop stimulator on 50 patients with stroke. Patients received 10-120 hours of treatment during 2-5 weeks. The percentage of excellent results decreased with increasing time from the lesion and increased with increasing the number of treatment sessions. They emphasized in their study the effect of FES on the reduction of spasticity and reported as being the most important factor in the improvement. They concluded that good FES candidates represent 20% of the ambulatory hemiparetic population. They did not do any gait assessment of the patients nor did they show the effect on the different gait parameters.

Waters et al (1985) followed up 16 patients with implantable Peroneal stimulator after 10 years of the implantation. Infection and progressive nerve damage were the most common negative findings in these patients.

A study by Strojnik et al in 1987 evaluated the use of implantable Peroneal stimulator by 20 hemiplegic patients for the treatment of foot drop. They found that patients used the stimulator for longer periods and extended walking distance and increased walking velocity were observed.
Stanic et al (1991) reviewed the use of foot-drop stimulators and stated that the different versions of Peroneal electronic braces have remained the only routinely used orthotic stimulators to date. The reason probably lies in the fact that the results using FES foot-drop stimulators are better than the those with passive braces, when taking into account the efficient active correction of equinovarus,

low cost, encumbrance level, safety, esthetic appearance and of course patient acceptance of FES orthosis.

To achieve optimal results they suggested general principles to follow which were developed over years of practice in Ljubljana:
1) The orthosis has to permit the patient to perform activities which would not be possible without it.
2) The device must serve a real need.
3) The device should provide function which can not be achieved by bracing.
They reviewed the use of the different types of the commonly available Peroneal stimulators (FEPA10, Microfes, IPPO) in the stroke population. Analysis of the results of their experience revealed the following factors to be important for orthotic use of Peroneal stimulators: miniaturized size, individually adjusted stimulation sequence, walking rate dependent control principle, short connecting wires and attachment below the knee, esthetic appearance, and implantable electrodes. The IPPO implant, in their experience has been the most often requested device by active patients to date. The decrease of the tonic component of spasticity in the gastrocnemius muscles due to continuous FES use was the most favorable effect.

Thirty five hemiparetic patients with implanted Peroneal stimulators were evaluated by Kljajie et al 1992. Significant improvement of gait was found although in some cases an excessive eversion of the foot was observed. Nine of the patients had re-implantation because of displacement of the stimulation electrodes after an average time of 3.5 years of proper functioning of the implant.

Kralj et al (1993) and (1995), in their review of the use of FES in the rehabilitation program stated that of the 2500 hemiplegic patients evaluated over the last 10 years in Ljubljana, 1575 were candidates for a lower limb FES program. In assessing the Peroneal stimulator in 670 patients, 80% used FES only during their rehabilitation program, while 20% remained long term users. In a more recent work published by the same group, using a smaller and more cosmetic device (Microfes), out of the 120 patients reviewed 80% decided to continue using the system at home. This is the largest review study of the use FES in stroke patients in the literature.

In England, Burridge et al (1996) investigated the clinical use of Peroneal stimulator (Odstock dropped foot stimulator) in 56 patients; 27 of them were hemiplegics. They found 86% compliance, and 15% increase in walking speed after using the system for more than 3 months.
A more recent study by Granat et al (1996) evaluated the orthotic and therapeutic use of Peroneal stimulator in 17 adult hemiplegic patients. They concluded that Peroneal stimulator applied in the late stage of rehabilitation would have a role in management of foot-drop in a selected patient population specially with medio-

lateral instability of the foot and reduced ground clearance in the swing phase leading to foot contact.

1.2.6.2. DUAL CHANNEL FES:

The dual channel stimulator was developed to close the gap between the bulky 6 channel and the single channel stimulator in therapeutic FES use. The following are several examples of combination for dual channel stimulator.

- stimulation of the soleus muscle in order to provide or correct the push-off in the terminal stance and preswing phases, together with stimulation of the Peroneal nerve for correction of equinovarus during the swing phase later on
- stimulation of the Peroneal nerve with stimulation of the gluteus medius and minimus muscles in order to prevent hip adduction in the terminal swing phase, also in some patients contralateral pelvis drop-in the stance phase.
- stimulation of the Peroneal nerve in the swing phase together with stimulation of the quadriceps muscle for correction of knee extension in the terminal swing initial and mid-stance phases.
- stimulation of the quadriceps muscle in the terminal swing phase and during the stance phase together with stimulation of the gluteus maximus throughout the stance phase to enable weight shift to the affected lower limb.

Dual channel stimulator FES was used by Cozean et al (1988) as part of a study to examine the effect of biofeedback and FES on stroke patients. The dual channel stimulator used with a foot switch comprises stimulus to contract the tibialis anterior during swing phase and the gastrocnemius during the stance phase of the gait cycle. Combination of FES with biofeedback resulted in statistically significant improvement in knee flexion, stride length, and gait cycle time.

A programmable dual channel FES system was developed by Malezic et al (1992) to use as an orthotic device in 11 stroke and 10 brain injury patients. They assessed its use with regard to the programmable parameters, effectiveness during gait, and feasibility in clinical use. Improved gait parameters were recorded.

1.2.6.3 MULTI CHANNEL FES:

After their experience with the foot-drop stimulator, Kralj et al (1970) began to study the effect of multiple muscle stimulation in the hemiparetic patient. With a 3 channel stimulator, it was found that walking was easier.

Stanic et al (1978) studied hemiparetic patients qualitatively and quantitatively with multiple channel surface stimulator of the lower extremity. They found that it corrects most of the typical gait anomalies in hemiparetic patients. The average degree of the correction was greater in the swing phase than in the stance phase. There was no long term follow up or control group in the study. They

were faced with problems of control and graduation of stimulation sequences and a more exact synchronization of stimulation to the gait.

In their review of the use of FES in stroke patients, Stanic et al (1991), reviewed the use of multichannel FES stimulator. They assessed the effectiveness of a 6 channel FES over 2-3 weeks in a group of 20 patients. Patients with severe disabilities who were not able to walk prior to six channel FES therapy can regain the ability to walk after the therapy and can continue the therapy with less demanding single or dual channel FES stimulators. The main problems with this therapy are the high demand placed on the therapist and the bulkiness of the 6-channel stimulator.

Using 30 channel portable stimulator, Ichie et al (1992) summarized its use in the Hokuryo FES clinic in Japan with stroke patients. The purposes of FES were reduction of spasticity and strengthening of atrophied muscles. Nebuya et al (1992), investigated the short term use of therapeutic electric stimulation in hemiplegic lower extremity patients. The motor ability was increased. The study was only conducted with 3 patients.

Reviewing the different studies done with multichannel stimulator in stroke patients, Kralj et al (1993) concluded that in general the daily multichannel placement and fixation is too clumsy and the donning and doffing is time consuming and impractical. They suggested that an implanted system is more suitable for future use.

Using functional electrical stimulation with intramuscular electrodes, ten channels and a microprocessor, Daly et al (1993) studied its effect on gait. After nine months of treatment the gait pattern significantly improved for knee flexion at toe-off, peak swing knee flexion and knee extension prior to heelstrike. However this was a single subject trial.

Marsolais et al (1994), studied the effect of a multichannel implanted stimulator and compared it with the conventional therapy in 4 subjects. Improvement was recorded.

The effect of multichannel electrical stimulation on standing, weight shift, and gait in stroke patients was investigated by Malezic et al (1994). Stance symmetry and rate of the weight shift improved significantly during the stimulation. Gait parameters including symmetry improved consistently after 25 stimulation sessions: velocity by 30%, cadence 5%, stride length 26%, and gait pattern was restored in all patients.
A comparative study to evaluate the effects of conventional therapy with multichannel FES on a group of 20 hemiparetic patients was done by Bogataj et al (1994). They assessed them for temporal distance variables and physical

status using Fugl-Meyer scale. The target group was patients with severe hemiplegia who were unable to walk independently. The progress during FES combined with traditional therapy was better than during conventional therapy and patients returned to their normal environment sooner. But the FES device used was heavy and impractical for regular clinical use.

Reviewing the literature many studies have been done on the use of FES systems in restoring locomotion in stroke patients. In the next two sections I will discuss the benefits and limitations of both FES systems and AFOs.

1.2.7. ANKLE FOOT ORTHOSIS vs. FUNCTIONAL ELECTRICAL STIMULATION

Some of the gait deviations in stroke patients can be addressed either with an AFO or FES. Each has its own advantages and disadvantages. The clinician has to decide which modality to use and at what stage of recovery.

- FES with hand or heel switch timed to coincide with the patient's individual gait pattern can be a useful adjunct to many gait training programs. There are gait deviations that can not be effectively managed through the use of FES or conventional AFO. Deviations of gait like pelvic retraction and depressed hip flexion with external rotation and adduction used to advance the involved extremity are not well suited to the use of FES because the affected muscles are too deep to be reached with surface electrodes.
- In case of insufficient knee flexion for swing, neither conventional bracing nor FES applied as an orthotic substitute are suitable choices for management. A KAFO is not capable of providing a knee-flexion assistance. Knee flexion for limb clearance during swing is for the most part passively provided as a result of momentum generated by hip flexion. Dorsiflexion assisted AFO and FES may be used to enhance a mass-flexion pattern of the lower extremity and increase knee flexion in swing phase.
- Early bracing is one of the problems therapists face in management of stroke patients which hinders the patient in using the affected muscles. FES provides effective joint positioning by eliciting activity from the weakened or inactive muscle groups. At the same time FES has the potential of increasing muscle strength.
- While a conventional orthosis provides the desired positioning during one phase of gait, it may interfere with motions essential to the normal completion of other phases of the gait cycle.
- An AFO used to produce dorsiflexion to correct the "foot-drop" gait pattern, may cause an increase in the flexion movement at the knee as the foot ankle complex moves from heel strike to foot flat. In a patient with insufficient quadriceps strength to stabilize the knee, this can result in knee buckling. When FES with a heel switch is used to provide dorsiflexion during swing, the electrical stimulus ceases upon weight bearing, thereby allowing the ankle to

move freely into plantarflexion from heel strike to flat foot with no increase in the flexion momentum created at the knee. This may be quite important for the hemiparetic patient when knee stability is a problem. The same device that stimulates the dorsiflexors for swing can also be used to stimulate the quadriceps for knee stability during stance, with both functions (working reciprocally) controlled by a single heel switch.

- FES devices, plastic AFOs provide good cosmoses when the patient wears long skirts or slacks. The new developments in FES technology have provided smaller units for FES stimulation with better cosmesis.
- FES may facilitate neuromuscular re-education by eliciting active muscle contraction, and provides an added afferent to the CNS.
- Conventional orthosis, may promote dependency which is undesirable if avoidable. However FES weaning from regular use of the device is easier (Packman 1992).

1.2.8. Limitations Of FES Usage

- Rapid stimulation of the muscles that are antagonists of moderately to severely spastic muscle groups may result in quick stretch and undesirable activation of the spastic muscles e.g. stimulation of tibialis anterior muscle in the presence of excessive gastrocnemius-soleus spasticity can result in facilitated plantarflexion, rather than desired dorsiflexion during swing.
- The heel switch used to trigger stimulation is pressure sensitive. Hemiparetic patients may not be able to have heel pressure. In this case the ankle would continue to dorsiflex because of insufficient weight bearing on the heel. This can be avoided by fixing the duration of the stimulus. Using new FES technologies such as the one used in our study can provide an alternative in some cases.
- Ankle mediolateral instability during stance phase can potentially be a limiting factor in the clinical application of FES in a some hemiparetic patient. It is the clinician's judgment to decide how much of this instability contributes to the safety of the patient when using the FES.
- Unnecessary muscle fatigue, balance impairment, inappropriately timed afferent input and cosmetically unacceptable posturing during static standing and sitting are limitation considered in the application of FES.
- Relatively small changes in the position of electrodes can dramatically influence effective joint positioning. Patients or attendants must be taught the proper positioning, battery replacement or recharging, gel application, skin inspection, and adjustment of intensity control.
- Discomfort is one of the complaints some patients using FES have. It is due to stimulation of the cutaneous sensory nerves. This will be dealt with in detail in a separate chapter.

- Safety is a primary concern because any error, whether human or mechanical, can increase risk of a fall.

1.3. Hypothesis:

Having reviewed the literature relevant to FES and studied the factors that has limited its clinical application, a clinical trial (the main project of the thesis) with a new single channel foot drop stimulator for stroke patients was conducted. The following statements were put forward to test in the trial:

- The advanced technology used in the new Foot Drop Stimulator and the active correction of dorsiflexion it provides over the conventional approach by using ankle foot orthosis, will increase the clinical applicability and the acceptance by patients and rehabilitation clinicians
- Proper selection, training and technical support are important factors in the short and long term compliance of patients using FES systems.
- The use of the new foot drop stimulator will improve the temporal gait parameters and walking efficiency.

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CHAPTER 2: EVALUATING A NEW FOOT DROP STIMULATOR FOR STROKE PATIENTS

2.1 INTRODUCTION

Stroke with resultant hemiplegia, is the leading cause of disability in the elderly in North America. It is the third most common cause of death after coronary heart disease and cancer. Currently there are about 3 million people who have survived stroke in the United States. It costs the Canadian economy $1.5 billion a year in terms of health expenditure and lost productivity and it costs the United States economy about $30 billion a year. Improved management has led to the increase in the survival of stroke patients by 40% in 1990 compared to 1980. This will increase the number of disabled individuals and the impact it has on the health system. In addition, the increased incidence with aging adds to the burden, especially with the trend of an aging population (Folger et al 1987, Veloso 1993, Agency for Health Care Policy and Research [AHCPR] 1995, Bronner et al 1995, Shahar et al 1995).

Stroke rehabilitation is multidisciplinary and deals with the different medical, physical and psychosocial issues facing the stroke survivor. Mobility is an important component of stroke rehabilitation and has profound effects on the rehabilitation process as a whole. In spite of this, during the last 10 years research and development of locomotion in stroke has not been a top priority in the programs of national agencies responsible for this field (Stanic et al 1991, Kralj et al 1993).

One of the abnormal gait patterns in patients with hemiplegia is foot drop; the inability to dorsiflex the foot during the swing phase of the step cycle. This gait pattern anomaly may result in other abnormal gait patterns. The conventional approach to foot drop is the prescription of an ankle-foot-orthosis (AFO). An AFO is a passive device which holds the foot in a fixed position and prevents it from dragging. The alternative approach is to stimulate the dorsiflexors of the foot during the swing phase of the step cycle (Oatis, 1995).

The rehabilitation of hemiplegic patients using Functional Electrical Stimulation (FES) was first introduced by Liberson et al (1960). The stimulus was applied to the Common Peroneal nerve to stimulate the pretibial muscles with the use of a heel switch. Later developments of FES technology are based on this basic idea. After that, many centers in Europe and the United States further developed this idea but its wide clinical applications remained limited. More recently, two studies in Great Britain have investigated the use of new technology foot drop stimulators with results emphasizing the importance of proper selection of patients and that long term follow up is needed to evaluate its effectiveness (Granat et al 1996, Burridge et al 1996). The largest population of stroke patients using foot drop stimulators was studied by the Ljubljana group

who claim 20% of the users remained long term users. The reasons for poor clinical applicability of these systems were poor selection of patients, improper positioning of the electrodes, bulky electronics, and deficient support to the user (Kralj et al 1993, 1995).

Foot drop stimulators provide active gait correction. Stimulating the dorsiflexors may correct foot drop but it does not correct other gait anomalies. More complex multichannel FES systems were developed to overcome the abnormal gait patterns but most of these systems are cumbersome to the patient who is already burdened with other medical and social issues. With the fast progress in medical technology, the future development of easy to operate and more efficient FES systems seems more realistic now than it was a few years ago.

The objective of the study is to clinically evaluate a new system of externally applied Common Peroneal nerve stimulation on the recovery of gait in stroke patients and comparing it with the conventional AFO approach.

2.2 METHODS

2.2.1 Subjects: This study took place as part of the Stroke Rehabilitation Program at the Glenrose Rehabilitation Hospital. Nine subjects have been recruited for the purposes of this study until now. This study is an ongoing study and larger numbers of subjects will be recruited as required to reach statistical significance in the result. The clinical trial and protocol was approved by the Ethics Research committees at the Glenrose Rehabilitation hospital and the University of Alberta hospitals.

Inclusion criteria: the criteria for subject selection were,

- first episode of anterior circulation cerebrovascular accident stroke resulting in hemiplegia
- stroke subjects having difficulty lifting up their foot while walking in the swing phase of the gait cycle (foot drop)
- stable medical condition
- ability to stand and walk for a distance of 10 meters with stimulation or assistance
- adequate cognitive and communication function to be able to give informed consent, understand the training instructions, and give feedback to the team in the satisfaction/dissatisfaction scale form given at the end of the study.
- willingness to participate in the project
- at first only recent strokes (less than 6 weeks) were included in the study and the subjects were supposed to be followed up for 6 weeks during their stay at the Glenrose Rehabilitation hospital. Due to the recent health system changes in the province of Alberta, subjects were admitted earlier and stayed for shorter periods at the hospital, so the decision was made to include both

recent and more chronic strokes. The ethics approval was extended to include chronic patients.

Exclusion Criteria:

- ability to walk at a rate greater than 0.8 m/sec at initial evaluation
- insufficient stamina (physical/mental/emotional) to tolerate the demands of the study in addition to regular therapy sessions.

The principal investigator attended the intake sessions of the acute stroke program at the Glenrose Rehabilitation Hospital between June 1995 to May 1996. Out of the 192 strokes admitted only 2 acute stroke patients were found appropriate for the project. As it is shown in table 2-2, since stroke patients have multiple medical problems, co-morbidities constitute the largest percentage of the rejections. The imbalance with low Berg scores, cognitively impaired subjects and good mobility recovery were the other major reasons for unenrollment in the project in the acute stroke program.

Out of the 17 chronic stroke patients referred to the team for assessment, seven were found appropriate for the foot drop stimulator and were enrolled in the study (table 2-1). The reasons for not enrolling them were different with each patient. The reasons were; poor balance, frequent falls, ankle medio-lateral instability, unmotivated patient, cardiac pacemaker, withdrawal reflex more than contraction was obtained, and hypersensitivity to electrical stimulation.

2.2.2 Apparatus:

The FES device used in the trials, known as WALKAID, is a fully self-contained unit (all components including electrodes, electronics, battery, and sensor are built in). It measures 10 cm x 7 cm and weighs 180 grams. It is applied to the lower extremity below the knee with the stimulating electrodes positioned over the Common Peroneal nerve at the fibular head. A self-positioning feature allows the device to be placed quickly and reproducibly from day to day. Closure is via Velcro straps. The stimulation of the Common Peroneal nerve is triggered by a tilt sensor. No other connection is needed and the device is easily donned and doffed by the subject or an assistant. For training and evaluation, and even stimulation, stimulus can be triggered using a hand switch or by sensors in the sole of the shoe. The tilt sensor has four adjustable parameters which can be adjusted according to the individual patient's needs. The on-threshold which is a preset reference angle (when the leg swings to the back) above which the stimulus turns on and an off-threshold (when the leg moves forward) turns the stimulus off. Stimulus duration and wait time are the other 2 parameters. The electrodes used are surface gauze button electrodes made conductive by wetting them in water. Software is provided with the device to help adjust the different variables to accommodate the differences in the gait of stroke subjects. The stimulus parameters of the device are: monophasic

wave, duration 200 μsec, frequency 25 Hz, current. WALKAIDS were supplied by Biomotion, Ltd. of Edmonton (Figure 2-1, 2-2, and 2-3).

2.2.3 Assessments:

1. Walking speed, stride length, cycle duration, and swing/stance ratio: These were recorded prior to starting the FES application, then at the end of the 2, 4, 6 weeks of the trial. Some subjects were followed for longer periods of time (up to 10 months) and further recordings were made. They were calculated from the video recording. These measurements were done in most subjects both at self selected and fast speeds. A total of at least four determinations were recorded using the video camera. The data was analysed later. These temporal parameters were recorded with the FES, and with either no FES or with the AFO if it was the normal mode of walking. Subjects were asked to walk both at their comfortable and fast speeds.
2. Walking Efficiency: Heart rate monitoring before, during and after walking at a comfortable speed for 6 minutes was carried out with FES, and either a standard AFO or no FES. It was done in one of the sessions. The subject was given enough rest after one test allowing the heart rate to return to a resting state before resuming the next test. The pulse was taken by a band around the chest and telemetered to a pulse rate measuring device (Polar ®). The pulse rate measuring device is similar to a wrist watch and was put on the subject's or the experimenter's wrist. Physiological Cost Index (PCI) and the walking distance were calculated at the end of the six minute walking (MacGregor 1981, Guyatt et al 1985). In a recent study the inter-day reliability of PCI was questioned but it showed the same trend as heart rate or VO2 (Carollo et al 1996).
3. Functional Independence Measurement (FIM): was determined at the beginning of the trial of FES. Subjects were usually above 90 to be able to enrol in the study. In FIM, mobility constitutes a small fraction of the total points. Minor changes in mobility might not have a significant effect on the total score. Using FIM was questionable after the start of the trial and we discontinued using it as an assessment criteria.
4. Patient/Family Satisfaction scale: This was filled out by the patient and family at the end of the study.

2.2.4 Procedure:

Patients who met the inclusion criteria were identified by the treatment team and were invited to hear more about the research project. The principal investigator contacted the patients and explained the project to the patient and family. Patients' consents were obtained.

During the initial visit, the appropriate position for the electrodes was determined by moving the electrode around on the skin until the optimal stimulation site was obtained.

The following steps were followed:

- with the use of a hand switch, optimal muscle contraction and its timing were obtained.
- with the use of trigger sensors in the insole of the foot, the patient was asked to walk to assess the stimulation of the muscles during the different phases of the gait cycle.
- FES device parameters including the threshold angles for turning the stimulator tilt sensor on and off to meet the needs of the individual patient were adjusted. Software is supplied with the device to optimize these parameters.

Patients in each session were videoed and the device was connected to the computer to analyze the different gait parameters. They were videoed in several conditions; with the FES, with an ankle-foot-orthosis and with neither if the patient can walk without any support. With the use of these walking aids, patients were videoed while walking with their comfortable normal speed and faster speeds, with and without cane, if that is safe and convenient to the patient.

Before allowing the device to be used at home, a detailed user manual was reviewed with and later given to the patient. Training using the FES device was done in co-ordination with the treating physiatrist and physiotherapist. Patients and nursing staff and family members were instructed in the use of the FES device and patients were asked to use the device during their regular walking activities. Data collection took place outside the regular exercise program so that this procedure would not interfere with the usual daily regular rehabilitation program of the patient.

If FES proved to be useful in a given patient, and the patient and the attending physiatrist and physiotherapist desired to continue the use FES, it was given to the patient for regular use. Patients were then called for follow-up.

2.2.5 Analysis of the Data:

After completion of the data collected, statistical analysis was done to compare the results before and after one month of the use of FES. Two way repeated measures ANOVA analysis was used to analyze the results of the different gait parameters before and after one month of FES use across different conditions. A paired t-test was used to compare the difference in heart rate and the physiological cost index in patients with and without FES use in the 6 minute walking distance.

2.3. RESULTS

A total of nine stroke patients are using the device on a regular basis. However one of the patient is using the device but was not included in the assessment because she could not come for regular assessments. The other patient at the

time of preparing this paper, has been using the device for few weeks only, not completing the 6 weeks period of the study. So the results represent 7 patients only.

All the subjects participating in the study except for one were dependent on their ankle foot orthosis. Because of the acquired gait patterns, changing to FES was an adjustment subjects had to make. There was a gradual change of the gait parameters and there may be more changes on long term follow up. Six subjects were more than two years duration from onset, so that their gait pattern changes are more profound; the change with FES may need more time than originally designed in the study.

The tilt sensor parameters are adjusted according to the patients' needs. The following are the mean and the range of values of these parameters for five patients who are using the WalkAid with tilt sensor in terms of voltage; on-threshold mean 1.12⇧0.26 (min. 0.73, max. 1.44), off-threshold mean 0.87⇧0.31 (min. 0.53, max. 1.28), stimulus duration mean 0.7⇧0.1 (min. 0.55, max. 0.82), and wait time mean 0.22⇧0.03 (min. 0.18, max. 0.25). The 2 patients using the WalkAid with the foot switch as the sensor, the values were the following; on-threshold mean 0.38⇧0.01 (min. 0.37, max. 0.39), off-threshold mean 0.25⇧0.01 (min. 0.24, max. 0.25), stimulus duration mean 0.46⇧0.095 (min. 0.39, max. 0.53), and wait time mean 0.38⇧0.13 (min. 0.29, max. 0.47)

There was no statistically significant difference in speed, stride length, and cycle duration in subjects when compared with FES and with AFO or without any aid. When subjects were asked to walk at a faster pace, there was a positive increase in their speed with FES, an observation not present when they walk at regular comfortable speed. Subjects with longer duration since the onset of stroke had minimal increase or even decrease in speed when using FES which is more evident in normal walk (Figure 3-3 to Figure 3-6).

Swing to stance ratio was the gait parameter that was found to be statistically significantly different before and after FES use. This is the result of either a decrease in stance phase or an increase in swing phase or both. This effect was seen both in normal and fast speed. The trend was due to the correction of this ratio as an early and late effect of FES (Figure 2-4).

The Physiological Cost Index (PCI) was tested for 5 subjects in the study. No statistically significant differences were found in PCI with and without FES (Figure 2-5). As noted from the graph, slow walkers had more difference in heart rate than fast walkers. Of the five subjects tested, 4 walked further in the six minute walk test with FES than without it. The subject who walked a shorter distance with FES had a baseline distance of walking that was considerably higher than the others.

When evaluating the patient's satisfaction, despite the minor changes objectively assessed in gait, the patients' response was very positive (figure 2-6). They all would like to continue using the device and would recommend it to others. Their response differs when asked about their ability to walk better with the device, but is still on the positive side. No patient dropped out of the study. Most of the patients were using it in their regular daily activities. One patient preferred to use it indoors only, especially in icy weather. Despite the fact the majority were AFO dependent before the FES use, they all abandoned their AFOs for FES device.
One patient experienced a carry-over effect of the FES for about two hours. There were other feelings which can not be assessed objectively, like "my feet feel lighter". This may be related to a decrease in spasticity.

2.4. DISCUSSION

The application of FES in Rehabilitation Medicine is often mentioned in the standard rehabilitation textbooks as one of the modalities in rehabilitation management. Since the first application of FES by Liberson et al (1960), there has not been any long-term clinical study in the literature investigating the use of FES. The argument has always been raised about the benefits of using FES versus the time spent by the patient to learn operating these systems, the high costs and the availability of alternatives. On reviewing the literature many FES systems have been patented but they remained in the archives with no or perhaps limited clinical applicability. The last FES system to gain approval by the FDA is the Parastep (Graupe et al 1996). It is used for spinal cord injured patients. However the compliance was low and long term use has not been established. The high cost and long training required were factors for the decreased Parastep clinical use. The upper limb implantable FES system developed by the group in Cleveland is pending approval from FDA and undergoing multicenter trial. On reviewing the proceedings of the last International FES society meeting in Cleveland (May 1996), very few clinical applications are noted despite the fact most of the studies presented deal with very advanced technology and neurophysiology. This study evaluated a foot drop stimulator which can be used by the selected stroke patient and prescribed and followed up by a rehabilitation clinician in a standard rehabilitation center setting.

The issue of safety is one of the major factors that has delayed any lower limb FES systems clinical applications. Lower limb FES systems should be robust with easy to use control designs in order to be used clinically. Previous studies related to foot drop stimulators were limited and had problems such as proper positioning, electrode systems, discomfort, and bulky electronics resulting in non-compliance of patients (Liberson et al 1960, Takebe et al 1975, Kralj et al 1993 &1995). The system used in this study addresses these issues. Proper positioning is done in the first setup session and later the positioning of the

garment secures repositioning in the same place. Patients usually do minor adjustments in the placement of electrodes and did not find it difficult to get the proper position. As reported by the previous authors any minor change in position may affect the balanced dorsiflexion with predominant eversion or even plantarflexion. Plantarflexion was seen more in the screened patients who had severe spasticity. Eversion was noticed in a few of our patients but with minor adjustment of the electrodes, patients could get more balanced dorsiflexion. In other patients mild eversion with dorsiflexion was accepted as long as there is clearance of the foot. The electrodes used caused the least discomfort as shown in Chapter 3. They are also simple to use and place. The device is small and easily donned and doffed.

All patients in the study, except for one, were using AFOs before the study and three of them were totally dependent on it. They used it for all their activities, putting it on in the morning and taking it off at bed time. Changing to a foot drop stimulator was a change that needed motivated subjects. After long time of AFO use, muscles are usually atrophied and the patients' gait pattern is AFO dependent. Patients have to adapt to the FES system, this may take time in order to restore to more normal gait pattern accomplished by the FES. Longer follow up is needed to assess the effectiveness of FES systems in the group of patients studied than the 6 weeks period. Only one patient continued using the AFO for outdoor activities.

Patients with severe ankle medio-lateral instability may benefit more from an AFO than foot drop stimulator. Granat et al (1996) in their study reported that by dorsiflexing and everting the ankle in the swing phase, this action improved inversion and heel strike during stance phase and enhanced the quality of gait. In our study we observed that patients with predominantly inversion anomaly were more stable on stance with FES. Because of safety concerns, subjects with foot drop but with prominent ankle medio-lateral instability were not included in our study.

Increase in speed has been reported by many authors as a measure for improvement in stroke patients. There was no statistically significant increase in speed in our study which agrees with the results from Granat et al. Burridge et al (1996) in their study showed a 15% increase in speed. Stroke patients have certain gait patterns which are difficult to change. The change from long term AFO use to FES has a definite negative effect since patients need time to adjust and to feel safe using FES which may decrease their speed. Longer term follow up is necessary to verify the results. Patients did better on a fast walk and the increase noted, although statistically insignificant, reflects that these patients have the potential to walk faster if instructed and supervised to do so (Bohannon 1992).

There was normalization of swing to stance ratio in stroke patients using the FES with a statistically significant difference when compared with an AFO or no aid. This reflects that there is correction of gait pattern towards normal.

Patients who had knee stiffness or hyperextension during stance were more difficult to deal with. The device used, with its built in sensor, depends on the angle the shank makes in relation to the orientation of gravity. Patients with knee stiffness can not incline their legs. So the angle made is either very small or negligible. The software available with the device permits the clinician to make the proper angle adjustments to change the angle of inclination. Two of our patients were given heel switches as sensors because the angle detected by the tilt sensor was not reliable to use as a trigger. These patients after training and use of the device will be considered for the tilt sensor. Training is very important before prescribing FES system to most patients. Basic gait training including weight shift and even step length was done prior to allowing home use of the devices.

Patients walked longer with FES than with AFO or without any orthotic aid. Their tolerance has increased. PCI was not statistically significantly different between the FES and AFO users or patients who used no aid. Slow walkers had more difference in heart rate than others. The PCI test was done on five patients only. More patients are needed to verify this preliminary result.

One patient (EW) had a noticeable increase in muscle strength in dorsiflexors from MRC grade 2 to grade 4. The patient was more than one year duration after onset. Natural recovery is unlikely to account for this increase. Most of the studies have shown that most recovery, both functional and neurological, occurs within the first 12 weeks post stroke (Jorgensen et al 1995). This was the same reason why we chose stroke patients of more than 12 weeks duration since onset to exclude any anticipated natural recovery. Further work would be required to determine whether early application of FES systems has any effect on recovery (Macdonell et al 1994).

Change of spasticity with electrical stimulation was reported by several investigators (Stefanovska 1988,1989, Crone et al 1994, Burridge et al 1996). This change happens over a long period of time and should be quantified in order to detect minor changes. Some of the gait changes, feelings like "it feels lighter", and carry-over effect for few hours reported in only one patient can be explained on the basis of decrease in spasticity. As part of the on-going research, our lab is looking at the change in spasticity quantitatively with electrical stimulation.

The subjects' response to the satisfaction evaluation was positive in all the

statements. They reported that they can easily use the device on a regular basis and would like to continue using the device. No one dropped out from the study. Patients' motivation is an important factor in the success of any FES clinical application. Compliance in using the foot drop stimulators differs among the different studies. Kralj et al (1993, 1995) reported that compliance was 20% in their 670 stroke patients. While the use of Microfes in 120 patients by the same group claimed 80% compliance. Burridge et al 1996 reported 80% long term users using Odstock foot drop stimulator in England. Our patient group is still too small to draw definite conclusions about compliance, but till now all the users are continuing the use of the foot drop stimulator. Proper education of the patients in the use of the device, the availability of support to answer questions or to solve technical problems, and most importantly giving enough time to patients to train using it are all important before giving it for regular use at home.

What is the percentage of stroke patients who can benefit from a foot drop stimulator? On reviewing the literature there is no study reporting the percentage of foot drop gait anomaly in stroke patients. There is a consensus that it is one of the common gait patterns post stroke. However clinicians think it is in the range of 10-15% (personal communication). Granat et al reported that it can applied to only 2% of the stroke population in their health facility. The principal investigator attended the intake sessions at the Glenrose Rehabilitation hospital for one year coordinating with the stroke team in finding the appropriate patients. Patients were admitted rather early post stroke when they have to deal with many other medical and psychosocial issues. In addition, cognitively most of these patients were not stabilized enough to give a consent form. Consequently an exact percentage is difficult to conclude. Proper selection of patients is of an utmost importance in the long term success of any FES application.

Tables:

Subject	Age	Condition *	Walking Aids **	Months since onset
SM	48	R-CVA	AFO, CANE	30
RH	56	L-CVA	AFO, CANE	24
MZ	72	R-CVA	CANE	26
EW	55	L-CVA	NONE	16
CE	55	L-CVA	AFO, CANE	36
JC	77	L-CVA	AFO, CANE	25
AF	71	L-CVA	AFO, CANE	5
LK	38	L-CVA	AFO	3
JP	48	L-CVA	AFO	2

Table 2-1: Stroke subjects details at the start of the study.
* CVA: cerebrovascular accident. ** AFO: ankle foot orthosis

Reason for unenrollment	No. of Patients	Percentage
Enrolled	2	1.0
Brainstem or cerebellar lesion	16	8.3
Imbalance (low Berg score)	36	18.8
Impaired cognition and memory	16	8.3
No foot drop	29	15.1
Aphasia or Dysphasia	12	6.3
Multiple strokes	9	4.7
Co-morbidities	46	24.0
Low physical tolerance	3	1.6
Severe left neglect	7	3.6
Social reasons	8	4.2
Miscellaneous	8	4.2
Total	192	100.0

Table 2-2: The number of stroke patients that were admitted to the acute stroke program at the Glenrose Rehabilitation Hospital between June 1995 and May !996 and the reason for not enrolling them in the project.

Patient (N Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)			0.73	0.64
RH (AFO)	0.59	0.50	0.54	0.55
MZ	0.29	0.29	0.30	0.30
JC (AFO)	0.34	0.34	0.33	0.33
EW	0.89	0.87	1.24	0.75
AF (AFO)	0.41	0.42	0.45	0.43
LK AFO)	0.65	0.75		
JP (AFO)	0.53	0.59		

Table 2-3a: The speed (m/sec) of patients walking with their normal pace before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
N= normal

Patient (F Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)	0.91	0.82	0.83	0.82
RH (AFO)	0.61	0.69	0.68	0.71
MZ	0.41	0.33	0.42	0.39
JC (AFO)	0.43	0.41	0.40	0.39
EW	1.05	1.08	1.51	1.31
AF (AFO)	0.60	0.59	0.55	0.64
LK AFO)	0.90	1.00		
JP (AFO)	0.81	0.95		

Table 2-3b: The speed (m/sec) patients walking fast before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
F= fast

Patient (N Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)			0.90	0.78
RH (AFO)	0.85	0.76	0.78	0.85
MZ	0.77	0.78	0.74	0.73
JC (AFO)	0.67	0.72	0.70	0.72
EW	1.10	1.08	1.30	0.89
AF (AFO)	0.70	0.69	0.73	0.66
LK AFO)	0.88	0.92		
JP (AFO)	0.84	0.84		

Table 2-4a: The stride length (m) in patients walking with their normal pace before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
N= normal

Patient (F Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)	0.96	0.89	0.94	0.95
RH (AFO)	0.83	0.94	0.92	0.97
MZ	0.82	0.77	0.85	0.82
JC (AFO)	0.64	0.84	0.78	0.81
EW	1.16	1.19	1.51	1.37
AF (AFO)	0.79	0.76	0.73	0.85
LK AFO)	1.02	1.09		
JP (AFO)	0.98	1.06		

Table 2-4b: The stride length (m) in patients walking fast before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
F= fast

Patient (N Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)			1.22	1.22
RH (AFO)	1.46	1.55	1.43	1.53
MZ	2.69	2.77	2.52	2.43
JC (AFO)	2.13	2.13	2.14	2.22
EW	1.23	1.26	1.05	1.18
AF (AFO)	1.79	1.65	1.61	1.56
LK AFO)	1.38	1.25		
JP (AFO)	1.62	1.43		

Table 2-5a: The cycle duration(sec) in patients walking with their normal pace before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
N= normal

Patient (F Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)	1.06	1.09	1.13	1.15
RH (AFO)	1.36	1.37	1.35	1.38
MZ	2.00	2.36	2.01	2.10
JC (AFO)	1.92	2.02	1.96	2.19
EW	1.16	1.12	0.95	1.04
AF (AFO)	1.34	1.30	1.33	1.32
LK AFO)	1.15	1.10		
JP (AFO)	1.20	1.12		

Table 2-5b: The cycle duration (sec) in patients walking fast before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
F= fast

Patient (N Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)				
RH (AFO)	0.51	0.63	0.54	0.48
MZ	0.31	0.42	0.33	0.37
JC (AFO)	0.35	0.47	0.30	0.39
EW	0.48	0.55	0.62	0.56
AF (AFO)	0.38	0.40	0.39	0.38
LK AFO)	0.46	0.56		
JP (AFO)	0.37	0.50		

Table 2-6 a: The swing/stance ratio in patients walking with their normal pace before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
N= normal

Patient (F Walk)	Before FES regular use		After 6 weeks of FES regular use	
	Normal Mode	FES	Normal Mode	FES
SM (AFO)	0.62	0.48	0.61	0.61
RH (AFO)	0.57	0.63	0.59	0.53
MZ	0.43	0.49	0.42	0.49
JC (AFO)	0.44	0.45	0.37	0.41
EW	0.52	0.56	0.81	0.67
AF (AFO)	0.42	0.45	0.36	0.52
LK AFO)	0.52	0.59		

Table 2-6 b: The swing/stance ratio in patients walking fast before and 6 weeks after FES use.
Normal mode= mode patient used in mobility whether AFO or no aid.
F= fast

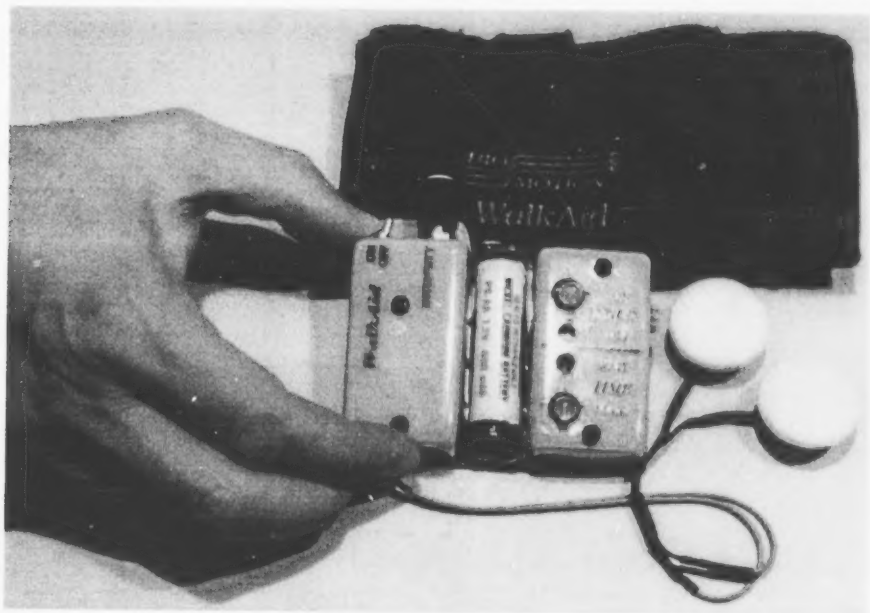

Figure 2-1: WALKAID® is the foot drop stimulator used in the study. It has a built-in sensor and uses 2 cotton electrodes.

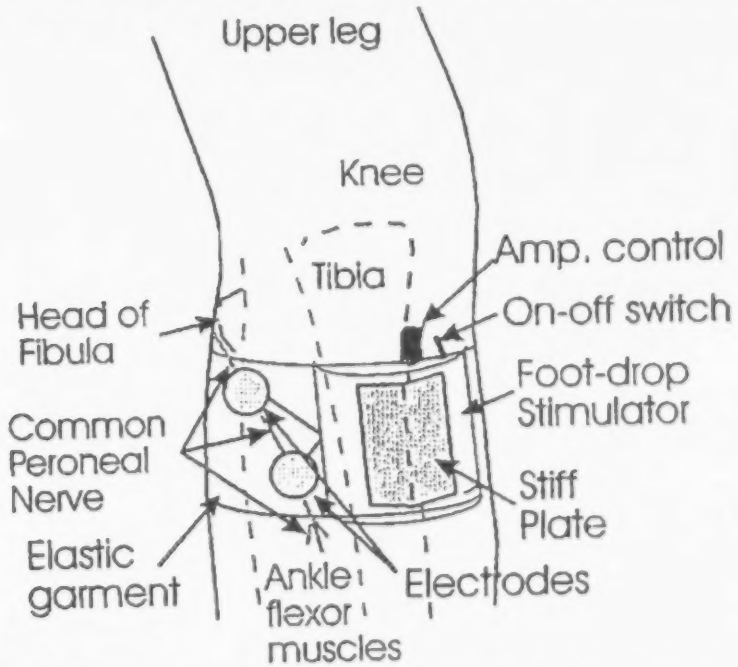

Figure 2-2: A schematic showing the positioning of the foot drop stimulator at the upper end of the tibia. The active electrode is positioned over the Common Peroneal nerve as it passes over the head of the fibula.

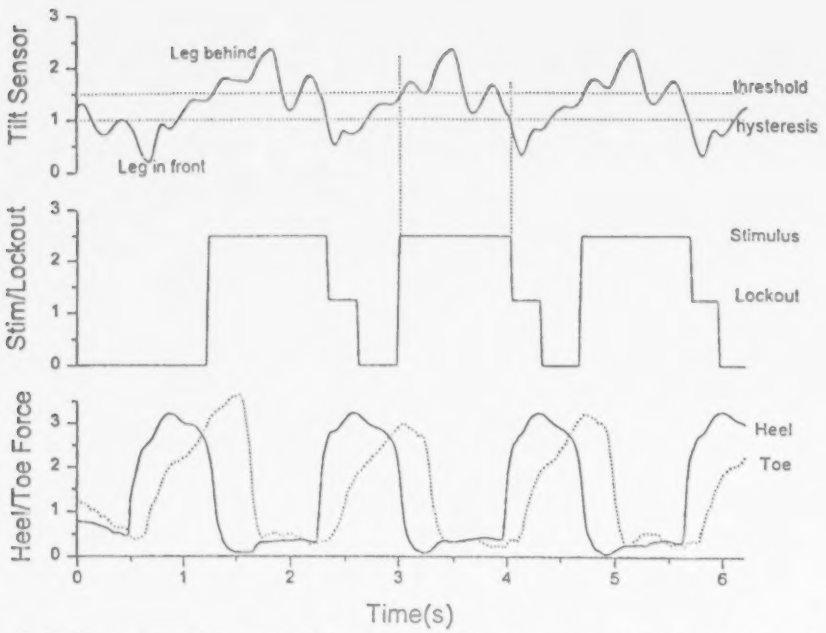

Figure 2-3: The signals recorded from the software used with the device. In the preswing phase, a threshold angle is reached, and stimulation starts. This coincides with heel lift and the start of swing phase. In the lock-out period there is no stimulation.

Figure 2-4: The ratio of swing to stance before and after FES use compared to the normal mode (AFO or no aid). The normal swing/ stance ratio is 0.67 .

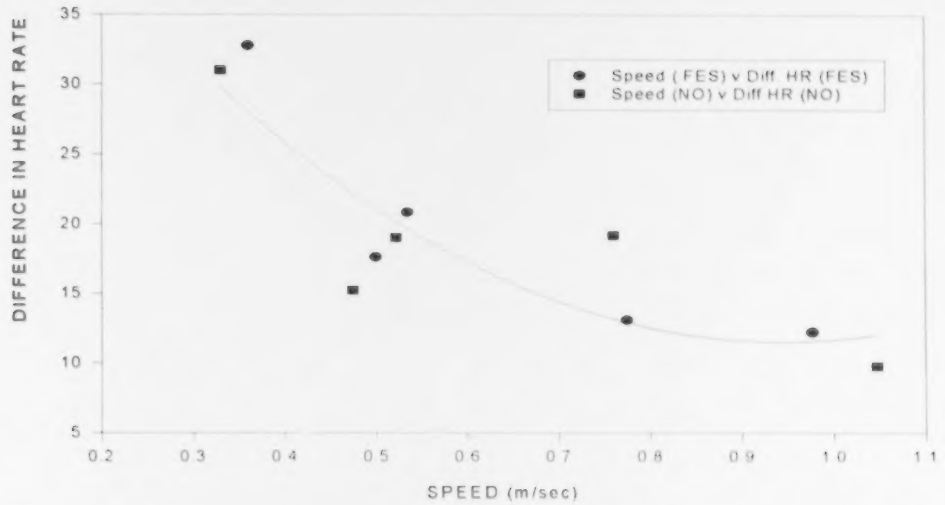

Figure 2-5: Physiological Cost Index. Difference in heart rate plotted against speed. Slow walkers had higher difference in heart rate.

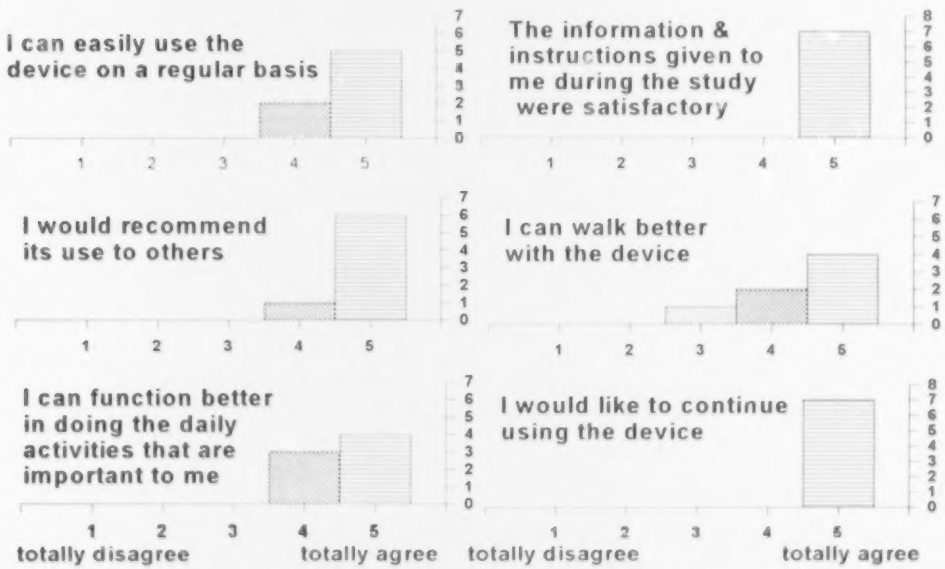
I can easily use the device on a regular basis
The information & instructions given to me during the study were satisfactory
I would recommend its use to others
I can walk better with the device
I can function better in doing the daily activities that are important to me
I would like to continue using the device
totally disagree
totally agree
totally disagree
totally agree

Figure 2-6: Patient satisfaction evaluation

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CHAPTER 3: MINIMIZING DISCOMFORT WITH FUNCTIONAL ELECTRICAL STIMULATION

3.1 INTRODUCTION

Functional Electrical Stimulation (FES) has been increasingly used as one of the therapeutic modalities in rehabilitation medicine especially in subjects with upper motor neuron lesion such as stroke, spinal cord injury, multiple sclerosis and other diseases (Stanic 1991, De Vahl 1992, Kralj et al 1993). The excitation of the neuromuscular tissue can be produced by transcutaneous, percutaneous, or subdermal stimulation. Transcutaneous is obviously least invasive and is the most commonly used type (Popovic 1992). In addition to the motor nerves, transcutaneous electrical stimulation causes stimulation of the cutaneous sensory nerves which can lead to the perception of pain and touch.

FES was first introduced by Liberson et al in 1961. In hemiplegic subjects the Common Peroneal nerve was stimulated in the swing phase of the gait cycle, by stimulating the ankle dorsiflexors to help subjects clear their feet while walking. They reported that one of the problems they faced was the pain felt at the site of stimulation. The same limitation was also found in a later study by Takebe et al (1975). Despite the advancement in FES technology, surface electrodes remain the most commonly used electrodes. A limited number of studies have been done to minimize pain and discomfort felt at the site of surface electrodes by adjusting the different parameters of the stimulus (Baker et al 1993, Gracanin et al 1975, Milner et al 1965, Moreno-Aranda et al 1981). Frequency, duration of the pulse, type and size of the electrode, and optimal position of the electrode to produce a designated contraction of the dorsiflexors of the ankle were the parameters evaluated in this study.

Most subjects with stroke or incomplete spinal cord injury have a partially intact sensory system so the potential problem of discomfort with stimulation is present.

To date, all comparison studies have been done evaluating normal or near normal subjects, and the immediate translation of this information to a variety of patient diagnoses may lead to some inaccuracies (Baker et al 1993). Our study was designed to test the different parameters in both normal subjects (NS) and neurologically impaired subjects (NIS).

3.1.1 Electric Stimulus Parameters:

Electrical stimulus has certain features. The following is a summary of these features.

Polarity: Pflueger's law indicates that under normal physiological conditions, less current is required from a cathodal (negative) stimulus to evoke a muscle

contraction of a given strength than an anodal (positive) stimulus. The negative electrode is often used to evoke the muscle contraction (De Vahl 1992).

Waveforms: a variety of waveforms are available in the electrical devices. Two waveforms have been used traditionally for neuromuscular electrical stimulation: monophasic and biphasic. Biphasic pulses can be asymmetrical or symmetrical. Both waveforms allow an equal amount of current to flow in either phase, thus avoiding undesirable electrochemical effects and possible skin irritation. Baker et al (1988) reported a relatively preferred choice of either symmetric or asymmetric biphasic waveforms over the monophasic paired spike waveforms in both upper and lower extremity stimulation. However Wong (1985), found that monophasic paired spike waveforms were better tolerated by the subjects when compared with an asymmetric biphasic square wave pulse applied to the plantar flexors. Diletto et al (1992) found that no waveform consistently provided the most comfortable muscle contraction. Initially both monophasic and biphasic waveforms were tested, but subjects reported no consistent differences.

Amplitude: the intensity or amplitude of the current is measured by the height of the waveform as it deviates from the isoelectric line. As amplitude increases there is an increase in the number of motor units recruited and subsequently an increase in muscle force (Baker et al 1993).

Duration: many neuromuscular stimulating devices have a fixed phase duration between 200-400μsec. If the duration is fixed, muscle force can be adjusted by varying current amplitude. During electrically induced muscle contraction, a phase duration of 300μsec was preferred for comfort over a narrower or wider phase duration (Gracanin et al 1975). With low duration such as 50μsec, a greater amplitude of current is required to produce a pulse charge sufficient to generate muscle contraction. The increased amplitude also is sufficient to recruit small diameter afferent fibers that elicit a painful sensation when stimulated. Similarly, a duration of more than 1000μsec generates a pulse charge sufficient to recruit both motor and pain sensitive axons.

Frequency: low frequencies generate twitch contractions, allowing little sustained tension in the muscle. Low frequency stimulation may be used to locate motor points. Between about 15 and 30 Hz, the muscle contractions are fused with the resultant smooth contractions. This type of contraction allows the maximum force to be generated in the muscle. Clinically it is often desirable to limit the frequency to the minimum needed to create a tetanic contraction. At higher frequencies, neuromuscular fatigue takes place at the level of the neuromuscular junction (De Vahl 1992). Another factor potentially limiting stimulated contractions is fatigue of the muscle fibers themselves, due to metabolic exhaustion of the contractile mechanism (Baker et al 1993).

Duty cycle: to ensure that the muscle does not fatigue excessively and to effectively exercise the target muscle, the electric stimulus may be automatically turned on & off. The on and off times are often expressed as a ratio. The patient's diagnosis and degree of muscle weakness should be considered when selecting the preferred duty cycle for initiation of neuromuscular stimulation. On/off cycling of neuromuscular electrical stimulation is used primarily to maintain quality muscle contractions over extended periods of time (Baker et al 1993). Frequency and duty cycle must be considered together when adjusting parameters for an optimal neuromuscular stimulation program. Increasing off times and/or reducing frequencies are recommended when muscle fatigue is evident (De Vahl 1992).

Ramp times: to increase the comfort of stimulation, the circuitry of a stimulator may be designed to recruit motor units gradually, rather than abruptly where all motor units are excited at the same time. One method to create this "ramp" effect is to increase the amplitude of the pulse train slowly. Ramp down may contribute to the effectiveness and safety of some treatment programs (Baker et al 1993).

3.1.2 Electrode - Cutaneous Interface

During the passage of current from the electrode to a muscle fiber the stimulus passes through different mediums of varying characteristics during which the means of transduction changes from electrical to chemical to ionic. The stimulus waveform is transformed predominantly by a capacitive characteristic in the outer layer of the epidermis, so that when the stimulus reaches any excitable tissue, whether sensory or motor, it is smoothed. The skin not only transforms the stimulus waveform but can also cause pathways of charge density in certain regions. It is in these high density regions that any damage to the tissues may happen. The interface between the natural and the technical parts of electrical stimulation (e.g. FES orthosis) such as the electrode attachment to the patient represents a major limitation to electrical stimulation. The limitation involves many factors (Day 1984):

1. The effectiveness of the stimulus waveform, both in sustaining depolarization within the target muscle and causing minimal excitation of sensory mediators.
2. The distortion of the stimulus waveform due to frequency dependent skin impedance.
3. The dispersion of charge due to the effects of the electrode tissue barrier.
4. The changes in the conductive pathways due to relative movement of tissue structures between the target tissue and the skin.

3.1.3 Electrode Size & Type

In general, electrodes should be no smaller than the size of a dime if used for prolonged stimulation periods to avoid concentration of current, sensory discomfort, and possible burns (Balmaseda et al 1987, De Vahl 1992).

Placement of active electrodes should be avoided over scar tissue or bony prominences because impedance is increased compared to normal skin and muscle. Close spacing of the electrodes encourages superficial passage of current, whereas increased spacing promotes deeper penetration of current. Exact positioning of the electrodes especially for FES Peroneal nerve stimulator for stimulating the Common Peroneal nerve is very important. Relatively small changes in the positions of electrodes might affect ankle dorsiflexion. Milner et al (1965), tested 11 healthy subjects by stimulating tibialis anterior and gastrocnemius. In all cases the chief determinant of pain seemed to be the total peak current, independent of the electrode size. Most patients in their study preferred stimulating electrodes of at least 2 square inches.

3.1.4 Pain & its measurement

Pain is defined according to the International Association For The Study Of Pain as "an unpleasant sensory and emotional experience associated with the actual or potential tissue damage or described in terms of such damage" (Arendt-Nielsen 1994). Pain and discomfort in humans are mediated by several different classes of nociceptive afferent fibers. Thermal and mechanical nociceptors have small diameter, thinly myelinated A delta fibers that conduct at about 5-30 m/s. Activation of these nociceptors is associated with sharp, pricking pain. Polymodal nociceptors are activated by a variety of high density mechanical, chemical and hot or cold stimuli and have small diameter unmyelinated C fibers that conduct slowly at 0.5-2m/s. Both A delta and C fibers are widely distributed in the skin as well as in deeper tissues (Jessel et al 1991).
Because of the subjective nature of pain and the individual variation in the individual response to pain, measurement of pain is difficult. Several methods are used (Hoffman 1993, Husisson 1983):

a) Verbal descriptor scale: by using 3-5 numerically ranked words, pain intensity is measured.
b) Visual analogue scale: is a commonly used method to measure pain intensity. It is easy to administer and score. It consists of a 10 cm line with verbal anchors at both ends and the individual is asked to mark their level of pain.
c) Numerical rating scale: of 0-100 or 0-10 can be used to measure pain intensity. It is probably the easiest to administer verbally, making it more practical for clinical use.
d) McGill pain questionnaire utilizes 20 lists of words that describe sensory, affective and evaluative dimensions of pain.
e) Measurement of pain behaviors in subjects along with pain measurement can be used in the follow-up of the response of these subjects to treatments.

The objective of our study is to assess the different parameters; frequency, duration of the pulse, electrode size and type, and the best position for optimal

contraction of the anterior tibial muscles causing the least discomfort to the subjects tested while still providing an adequate dorsiflexion of the ankle.

3.2 METHODS

Subjects: Ten normal subjects (6 males, 4 females), and 8 neurologically impaired subjects (4 spinal cord injury [one male and 3 females] and 4 stroke [3 males and one female]) were recruited for the purpose of this study. Mean ages for the NS was (39.43⇧11.69) and for the neurologically impaired subjects (NIS) (49.04⇧16.85). All spinal cord injured subjects had incomplete lesions. The two limbs were used for testing in one spinal cord injured subject. The sensation was preserved in the stroke group. They consented to participate in the study. Pain was measured using a numerical rating scale of 0 - 10. It is the easiest to administer verbally: zero being no sensation while 10 represents intolerable pain. We used the term discomfort instead of pain to avoid bias in the subject's rating.

Instrumentation: An electrogoniometer with 2 arms was strapped to the ankle and connected to an oscilloscope. A current probe was used to measure current in the active electrode. The oscilloscope was used to measure the degree of movement of the ankle in dorsiflexion. The Grass SD9 stimulator was used. This is a constant voltage stimulator with a transformer - coupled output.

Procedure: The subjects were seated in a relaxed position. The experiment was explained to them to alleviate anxiety. The anterior tibial muscle was selected for electrical stimulation in this study by stimulating at various positions along the Common Peroneal nerve from its origin in the popliteal fossa to the motor point of the tibialis anterior. Each subject's age, weight, and height were recorded.

1. The first step was to determine the best position for optimal stimulation of the tibialis anterior with minimal discomfort. This position was used to test the other parameters:
Position 1: in the popliteal fossa
Position 2: half way between 1 & 3.
Position 3: near the fibular head over the Common Peroneal nerve.
Position 4: between position 3 &5.
Position 5: motor point of tibialis anterior.
2. Different frequencies: 15, 20, 30, 40, 50 Hz.
3. Variable durations: 50, 100, 200, 300, 500, 1000 μsec.
4. Different types and sizes of electrodes were assessed. The electrodes tested were the available ones in the market. a) Multiweek (2.5cm diameter circular), b) Multiweek (4.5cm sided) square, c) Electrotrace, d) Karaya gel, e) cotton electrode. In all of these the indifferent was 4.5 cm square Multiweek electrode, f) Both indifferent and active electrodes are cotton electrodes, g) WALKAID:

which has 2 cotton electrodes and has been used for the main clinical trial in chapter two.

The subjects were assured that the discomfort felt during stimulation is short lived and will cease with discontinuation of stimulation. Before giving the tetanizing stimulus, a low frequency stimulus was given to test the degree of contraction. Subjects were told that if the stimulation was intolerable we would stop. While maintaining the same level of contraction (dorsiflexion of the foot) measured by the goniometer, the different parameters were studied in respect to the discomfort grade subjects feel.

3.3 RESULTS:

The trend shows that the discomfort felt by subjects, both NS and NIS increased gradually and significantly with increase in frequency, despite the decrease in stimulus intensity so that the movement remains the same. However discomfort grade rating was higher for the NIS than NS group. A t-test was used to compare the differences between the NS and NIS groups using the same frequency. No statistically significant differences were found in the various frequencies (Figure 3-1). The current needed to obtain the same dorsiflexion of the ankle as measured by the goniometer decreased with increasing frequency. This trend applies to both NS and NIS, but more with NIS (Figure 3-5).

There was no significant trend with increasing durations in NS group, while the discomfort grade increased significantly with increasing duration in NIS group. When comparing the NIS and NS groups using unpaired t-test, only at 500μsec duration there was significant difference (Figure 3-2).

When assessing the different types and sizes of electrodes, although the cotton electrode showed the least discomfort, no statistically significant difference was shown when comparing the discomfort grade of the different electrode types. Using unpaired t - test, no statistically significant difference was found between NS and NIS when comparing the means of the discomfort grade using the various types of electrodes (Figure 3-3).

A lower current was needed for stimulation in position 1 (popliteal fossa) and position 3 (over the fibular head) both in males and females. While position 4 and 5 i.e. over the muscle needed a higher current for stimulation. Using one way ANOVA, a statistically significant difference was found between the different positions. However no statistically significant difference was found between males and females (Figure 3-4).

3.4 DISCUSSION

With the increasing use of neuromuscular electrical stimulation especially Functional Electrical Stimulation, the importance of causing less pain and discomfort has emerged as an essential factor in its successful application. The most efficient current form is the current form that provides the greatest force of muscle contraction with the least amount of discomfort to the NIS (Delitto et al 1992).

Discomfort is subjective so limited success has been achieved in identifying the comfortable stimulus parameters. In several studies either a single parameter was varied or a limited combination. No study has assessed all the parameters that play a role in stimulation.

The source of the discomfort can be from stimulation of the sensory pain fibers or from the muscle contraction. Personality variables may influence the feeling of pain and unpleasantness during the neuromuscular electrical stimulation (Delitto et al 1992, Ashley et al 1993).

Most of the studies in this field were done on normal subjects, but neurologically impaired subjects may have a different profile of discomfort or pain sensation (Baker et al 1993). In our study, at a designated muscle contraction level (dorsiflexion of the foot) the different parameters were studied. Although no statistically significant difference was found between NS and NIS in the frequency and duration parameters, NIS had a higher discomfort grade rating trends than NS in these parameters. This is a factor which should be taken into consideration when applying stimulation to the neuromuscular system with NIS. A larger number of subjects is required to verify the statistical significance of our data.

A monophasic square waveform was used in our study. Baker et al (1988), found that an asymmetric balanced biphasic square form was perceived as comfortable and was preferred to doublets monophasic waveform. On the contrary, Wong et al (1986) found that doublets monophasic current was less discomforting than the biphasic asymmetric square wave.

Our results have shown that there is a significant trend of increasing discomfort with increasing frequency. Kramer (1987) examined different frequencies, and reported that when the quadriceps femoris muscle was stimulated, more discomfort was felt at 20 Hz than with 50 Hz currents. At low frequencies the muscle contraction is not tetanizing or a higher current is needed to generate the same contraction which might cause more pain. Moreno-Arando et al (1981), found that 100 Hz alternating current was the optimal stimulation with least discomfort. To induce muscle strengthening, Stefanovoska et al (1985), in their study of 13 healthy subjects found that minimal discomfort was felt close to

fusion frequency which is about 25 Hz. Vodovnik et al (1965), reported that when patients were stimulated by rectangular wave, 20-40 Hz felt more comfortable. Higher frequencies causes faster fatigue by depleting the acetylcholine at the neuromuscular junction which makes them impractical for prolonged clinical use.

While discomfort increased significantly with increased durations in NIS, no significant increase was noted in the NS, even a negative trend. This substantiates the fact that NS and NIS differ in their perception of electrical stimulation. Gracanin et al (1975), found that pulse duration of 300 μsec causes minimum discomfort to the subjects. Vodovnik et al (1965), reported that pulse durations under 300 μsec are most agreeable in terms of producing adequate contraction and least discomfort.

With the advances of FES technology, many types of surface electrodes are on the market. One of the difficult decisions that clinicians using FES face, is which electrode to choose in terms of type and size to provide adequate stimulation and at the same time causing the least discomfort. Nelson et al (1980), studied different sizes and types of electrodes and found that stimulation of the quadriceps muscle with the largest electrodes produced the greatest and most comfortable knee extension torque. They found that the cleanest and most convenient electrode to apply is the pregelled electrode and concluded that these features make them highly desirable clinically. In an earlier report by Milner et al (1965), noted that most subjects in their study preferred stimulating electrodes of at least 2 square inches. Alon (1985), reported that if non-painful motor excitation is required, electrode size should be enlarged. In our study, several of the available and commonly used electrodes in the market were studied, although no statistically significant difference was found among the different electrode types, cotton electrode caused the least discomfort to NS and NIS.

Placement of the electrodes in the appropriate position is important in functional electrical stimulation. Minor changes in the position of the electrode may affect the required optimal contraction. In our study the Common Peroneal nerve was stimulated from its origin in the popliteal fossa to its insertion in the muscle at the motor point of tibialis anterior for the purpose of FES. From our experience we noted that slight changes in position can cause a dorsiflexion with predominantly eversion or inversion or a balanced one. The issue of exact placement and its role in electrical stimulation has not been addressed in the literature (Ashley et al 1993). Liberson et al (1960) and Takebe et al (1975) in their early studies of foot drop stimulators reported that proper placement of the electrodes was one the problems they encountered in clinical application of foot drop stimulators. We found that stimulation of the Common Peroneal nerve over the fibular head and the popliteal fossa causes the least discomfort. However in FES, because

of the frequent movement of the knee and subsequently the electrodes, the popliteal position is impractical for clinical use. When compared with other positions, position 4 and 5 required higher current and that caused more discomfort.

Females required higher current in all the positions than males. Although it was noted that in the positions over the muscle males needed more current because in order to obtain a contraction very high currents were required which were not tolerable by a few of our female subjects and were not recorded which had an effect on the results. The larger amount of subcutaneous adipose tissue in the females contributes to more current because the nerves are deeper and more discomfort felt by the subject. Placement of the active electrode over the fibular head, because of accessibility and less discomfort was the preferred position in the application of FES.

Avoiding skin sensory stimulation and subsequently discomfort by using implantable electrodes have been studied but with very limited clinical application. With advanced technology the research in implantable electrode systems has progressed tremendously in the last few years but still far from regular clinical use..

The other issue in FES application is how will the body react in terms of pain or discomfort to repeated long-term stimulation? Does habituation play a role? These are subjects for future research.

3.5 CONCLUSIONS

1. Discomfort at the site of the electrodes in Functional Electrical Stimulation is an important factor in its application.
2. When applying FES, discomfort can be minimized by utilizing the appropriate parameter values.
3. With increasing frequencies there is significant increase in discomfort grade in both normal subjects and neurologically disabled subjects.
4. No significant trend was found in discomfort with increasing durations in normal subjects while there was a significant trend in neurologically impaired subjects.
5. No statistically significant differences were shown when comparing the different types of electrodes. Cotton electrode seems to cause the least discomfort.
6. Appropriate placement of the electrodes is an important factor to be considered in FES application.
7. Discomfort in FES application in NS and NIS showed different trends, being higher for NIS in the different parameters.

8. A larger number of subjects are needed to verify statistical significance. Evaluating the effect of long term use of FES on the degree of discomfort are subjects for future research.

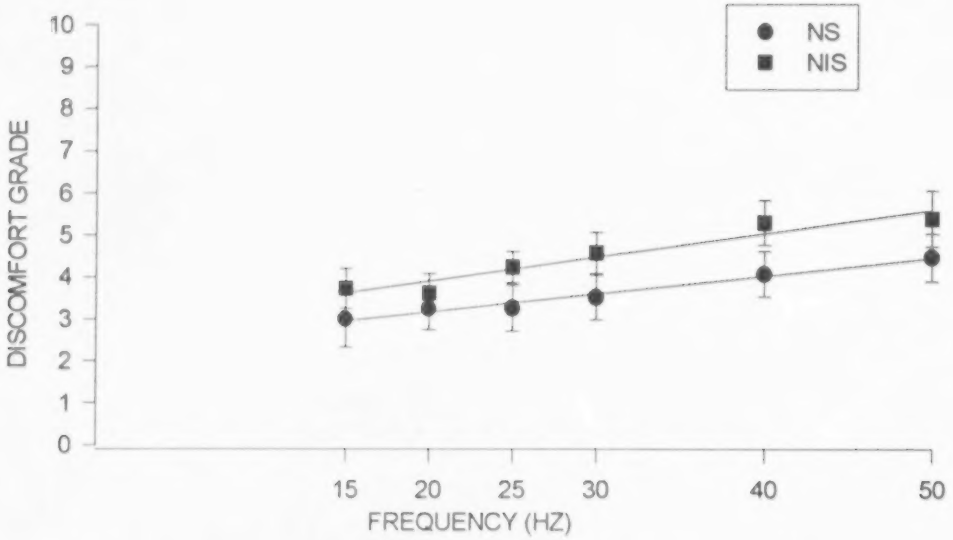

Figure 3-1: Discomfort grade felt by normal subjects (NS) and neurologically impaired subjects (NIS) with different frequencies. The trends show significant increase in both NS and NIS. Discomfort rating was higher for patients than normals.

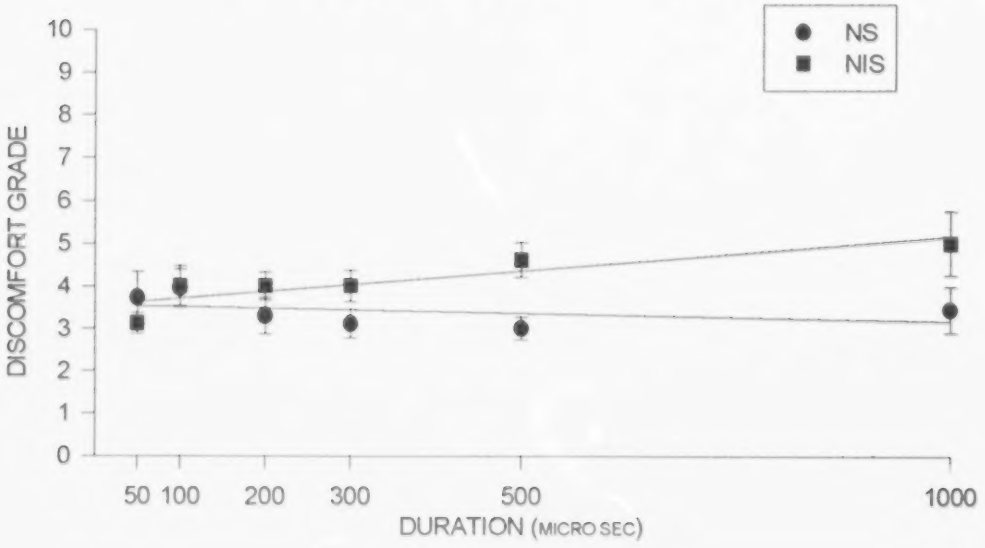

Figure 3-2: Discomfort grade felt by NS and NIS with different durations. No significant trend was found in NS while there was significant trend for patients.

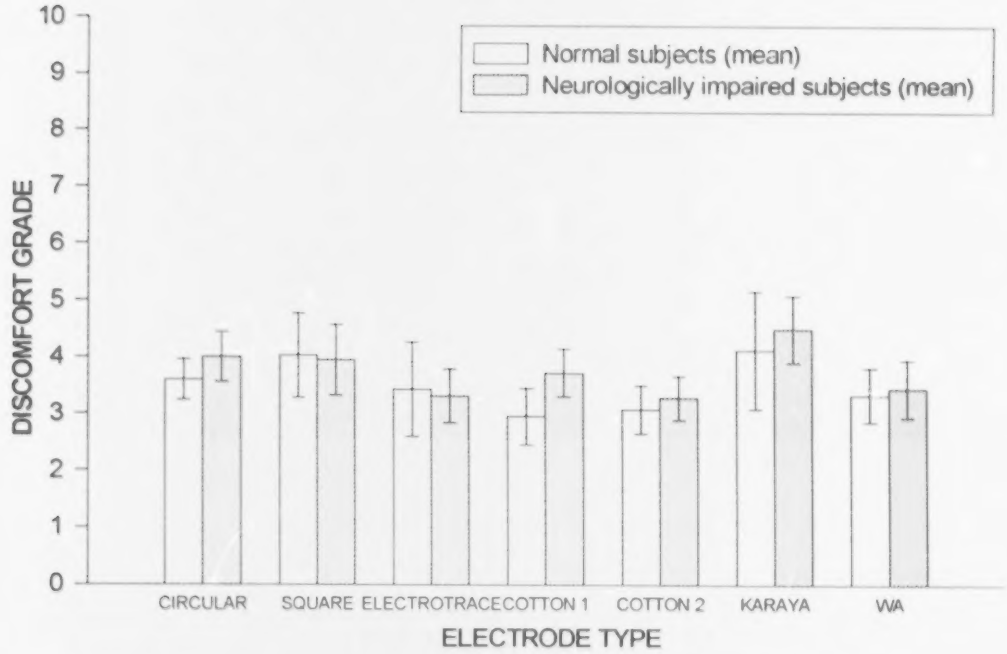

Figure 3-3: Discomfort grade felt by the subjects using different types of electrodes. Discomfort was less with the cotton electrodes.

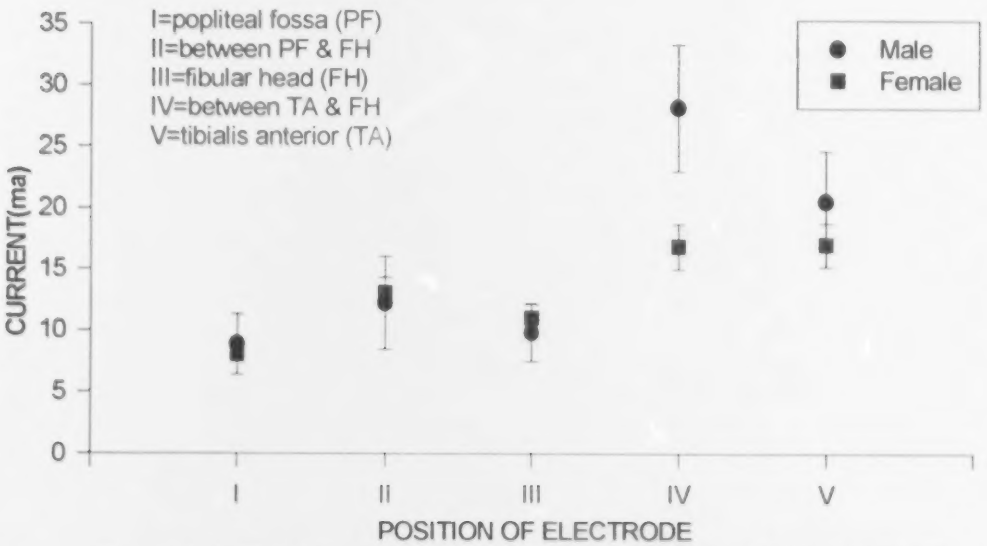

Figure 3-4: This figure shows the current needed to dorsiflex the foot by stimulating the common peroneal nerve from its origin in the popliteal fossa to its insertion in the motor point of tibialis anterior in both males & females

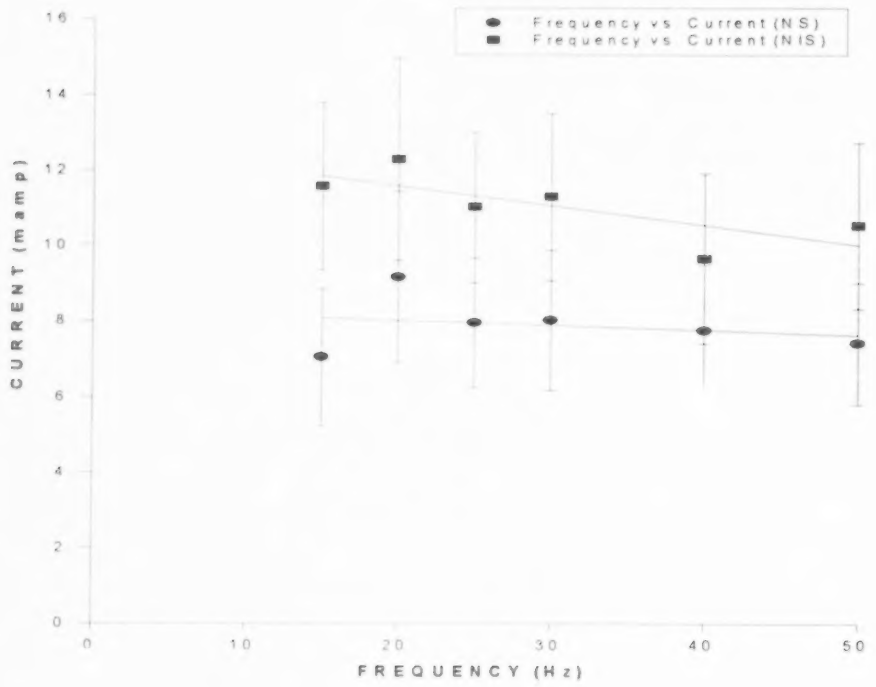

Figure 3-5: The different frequencies are plotted against the current needed to obtain the same contraction of the ankle dorsiflexors as measured by goniometer. The trend shows that with increasing frequency there is a decrease in the current. This trend is more with Neurologically Impaired Subjects (NIS) than with Normal Subjects (NS)

3.7. REFERENCES

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CHAPTER 4: GENERAL DISCUSSION AND CONCLUSIONS

4.1. GENERAL DISCUSSION

As we enter the third millennium and with the great advances in medical technology the need for applying these technologies (i.e. taking them from the laboratories to the patient) is a task that can be achieved only by the close collaboration of clinicians with people working in technology. Rehabilitation medicine is unique among the other medical fields in that it is multidisciplinary dealing with the disabled patients from all aspects, medical and social. Technology has played an important role as one of the disciplines in improving many of the rehabilitation techniques, providing a better life for many who are in need.

What is the role FES can play in the stroke rehabilitation process and what is the interaction of the stroke patient with this technology in terms of short and long term use? These were questions that I was asking myself when I started this project. With my background in clinical rehabilitation I was exposed to FES as one of the treatment modalities in stroke or spinal cord injuries and other diseases with only short paragraphs in the Rehabilitation textbooks. There are controversial results in the literature about the effects of FES. When the FES project was proposed to me by Dr. R. Stein, the first question that came to my mind was; as a clinician how much can I interact with FES technology or is it only people with the proper technical background that can deal with this technology? Definitely clinicians who are familiar with the musculoskeletal system can interact better with FES technology. At the end of two years the message to my colleagues in rehabilitation medicine; physiatrists, physiotherapists, neurologists, and orthopedic surgeons is that the first step to apply technology is being open to it, testing it, and discussing its applications and limitations.

The results of the clinical trial applying the one channel foot drop stimulator in stroke patients showed no significant changes in gait parameters before and after FES and when comparing it with AFO except for the swing/stance ratio. Nonetheless, the patients' evaluation of the FES system was very positive and all expressed their desire to continue using FES. Even with a simple FES system such as the one we used patients had to be properly educated in its use. Motivation of the patients is one of the important points in a successful FES application. Proper selection of patients is the key to any successful application of FES. Stroke patients are generally in an older age group with multiple co-morbidities. Any FES application has to be simple enough to be used on a daily basis, or compliance is questionable. Since it is an on-going study, regular long term follow up of the current users and recruiting more patients would give a better understanding of the compliance and benefits of FES use.

Technical problems were encountered initially with a few of the devices, but these were overcome by the availability of technical support and by encouraging patients to contact us whenever they felt that the system was not working properly. This policy was important in the compliance of these patients. Is support needed if it is applied to a larger scale in the population? From the initial set-up sessions to long term follow up, establishing a support system where the patient can contact the clinical team if any problem arises is very important in achieving successful compliance in community use.

What about the more complicated FES systems? Looking back at more than thirty years of FES history only a few applications have made their way into frequent patient use. Multichannel systems remained a very interesting research topic for researchers. The great advances in implantable electrodes and control systems may open new horizons for future clinical application of FES.

It is important to remember that application of FES deals only with one among many deficits that stroke or spinal cord injured subjects have. Most of our subjects were chronic stroke patients. Does early application of FES in the acute phase have an effect on the rate of recovery of acute stroke patient? This remains a subject for future research.

Discomfort from electrical stimulation and proper placement of the electrodes were the common problems encountered in previous applications of FES. In the clinical trial only one patient of those screened could not tolerate the electrical stimulation. Most of the patients found it a strange feeling at first and then got used to it. Discomfort with electrical stimulation was addressed in a separate study. While maintaining the same degree of muscle contraction (dorsiflexion of the foot), the different parameters of the electrical stimulus were adjusted to attain the minimum discomfort. To obtain a proper dorsiflexion of the foot proper placement of the electrode on the Common Peroneal nerve is essential. We noticed in a few patients that even very minor changes in the electrode placement can affect the type of contraction, predominantly eversion or plantarflexion. Having the electrodes fixed in the garment helps proper positioning to a great extent. In addition, after a short period of use patients can usually find the right position with minor adjustments. The importance of proper positioning in the use of FES was emphasized to patients.

The role of the patient in the successful application of FES is very important. In our study, we found that when the rehabilitation clinician at the Glenrose Rehabilitation hospital recommended or foresaw the potential benefit of FES to the patient, I contacted the patient and explained FES and his/her role in the study. The initial curiosity and trying any means to improve and hasten recovery are the things that motivate the patients to use FES. Later, only motivated

people continue the use of FES. Motivation of the patients is a very important factor in the compliance of patients.

A close collaboration between clinicians and rehabilitation technology people is very important in any successful FES application. The experience from our lab which involved a team of scientists and clinicians collaborating together in developing a successful clinically applicable FES systems is an example of how to approach FES application.

In addition to properly selecting a motivated patient for foot drop stimulator use, educating the rehabilitation clinician whether physiatrist, physiotherapist, or orthotist about FES and its potentials is essential in its successful application. The feedback from clinicians is very important for its proper clinical application. A sound marketing policy and a consistent postsale sale support system are important points to consider when commercializing any FES systems.

I would like to mention two other projects I was involved in which were very useful research experiences for me and carry potential clinical application. The Limb Rigidity Analyzer is a system developed by Dr. A Prochazka's group that can be used to measure spasticity in upper motor neuron lesion patients. I had the chance to test its application in a few patients with positive preliminary results. Quantitatively testing the effect of FES on spasticity using the Limb Rigidity Analyzer can be used in the on-going study. The use of FES in the management of orthostatic hypotension in spinal cord injured patients was a system developed by Dr. B Andrews group and I was involved in its testing. It reflects that potentially FES can have many applications in rehabilitation medicine. Well designed clinical trials to test the applicability of any technology is the key to its successful application.

The time I spent at the Division of Neuroscience-Rehabilitation Neuroscience group for the last two years was a very rich learning experience for me. Learning basic neuroscience, neurophysiology, proper research, and the clinical application of FES, I feel myself more equipped to resume my clinical career in Physical Medicine & Rehabilitation.

4.2 CONCLUSIONS

1) Stroke is the leading cause of disability in the adults. More than 3 million people are living with different degrees of disability due to stroke in North America.
2) Rehabilitation has an important role in the management of stroke patients. Proper selection of patients, starting early, and deficit specific management are important points in a successful stroke rehabilitation program.

3) Abnormal base of support, instability and defective limb clearance (foot drop) are common gait deficits in stroke patients.
4) An ankle foot orthosis is the most commonly used orthotic device for foot drop. It provides medio-lateral stability and helps clearing the foot during walking (swing phase). However, the passive nature of the device which limits movements around the ankle, its cosmesis, and bulkiness are problems in patient's compliance.
5) Foot drop stimulators were the first application of FES. Its widespread or long term use has been limited. They provide active movement of the ankle during walking. With new technology these devices are have become small, energy efficient devices.
6) WALKAID is a one channel foot drop stimulator with a built in sensor. Its role in improving gait in stroke patients was evaluated and compared with their normal mode of walking using either an AFO or no aid.
    - Stroke patients were assessed for temporal gait parameters (speed, stride length, cycle duration, swing/stance ratio). No statistically significant increase in speed, stride length and cycle duration before and after FES use and between it and their normal mode of walking at the end of 6 weeks period.
    - There was a statistically significant difference in swing/stance ratio after FES use which indicates a correction towards the normal gait pattern.
    - No statistically significant difference was reported in the Physiological Cost Index after FES use. However subjects had a tendency to walk further with WalkAid.
    - Subjects had a high satisfaction using FES.
    - High compliance was observed with no dropouts from the on-going study.
    - More subjects are needed to determine statistical significance.
7) Discomfort is one of the issues in the application of FES. The minimizing of discomfort using different combinations of stimulus parameters, electrode types, and different position of electrodes while maintaining the same degree of contraction was studied.
    - There was significant increase in discomfort grade with increasing frequencies in both normal and neurologically impaired subjects.
    - With increasing duration there was no significant increase in discomfort grade in normal subjects while there was a significant increase in neurologically impaired subjects.
    - No significant differences were shown between the different types of electrodes. Cotton electrodes seem to cause the least discomfort.
    - Appropriate placement of the electrodes is an important factor to be considered in any FES application.

- In general neurologically impaired subjects had a higher rating of discomfort compared to normal subjects.